POLLUTION CONTROL BOARD

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Standards for the Management of Specific Hazardous Waste and Specific Types of Hazardous Waste Management Facilities

2) Code Citation: 35 Ill. Adm. Code 726

3)

Section Numbers:	Proposed Actions:
726.180	Amendment
726.202	Amendment
726.305	Amendment
726.600	New Section
726.601	New Section
726.602	New Section
726.603	New Section
726.604	New Section
726.605	New Section
726.606	New Section
726.607	New Section
726.608	New Section
726.609	New Section
726.610	New Section

4) Statutory Authority: 415 ILCS 5/7.2, 22.4, and 27

5) A Complete Description of the Subjects and Issues Involved: The amendments to Part 726 are a single segment of consolidated docket R20-3/R20-11 rulemaking that also affects 35 Ill. Adm. Code 702, 705, 720 through 725, 728, 733, 810, and 811. The consolidated R20-3/R20-11 rulemaking updates the Illinois hazardous waste rules to incorporate amendments adopted by the United States Environmental Protection Agency (USEPA) during 2019. A comprehensive description is contained in the Board's opinion and order of May 21, 2020, proposing amendments in consolidated docket R20-3/R20-11, which opinion and order is available from the address below.

The Notice of Proposed Amendments for 35 Ill. Adm. Code 702, which also appears in this issue of the *Illinois Register* summarizes the broader rulemaking that is consolidated docket R20-3/R20-11. The Board directs attention to that Notice for elaboration.

Specifically, the amendments to Part 726 incorporate segments of USEPA's Universal Waste Aerosol Cans Rule into the Illinois hazardous waste regulations. The amendments include needed corrections in rule not directly related to USEPA amendments, including

a correction to prior amendments requested by the Joint Committee on Administrative Rules (JCAR).

Tables appear in a document entitled "Identical-in-Substance Rulemaking Addendum (Proposed)" that the Board added to consolidated docket R20-3/R20-11. The tables list the deviations from the literal text of the federal amendments and the several necessary corrections and stylistic revisions not directly derived from USEPA actions. Persons interested in the details of those deviations from the literal text should refer to the Identical-in-Substance Rulemaking Addendum (Proposed) in consolidated docket R20-3/R20-11.

Sections 22.4 of the Environmental Protection Act [415 ILCS 5/22.4] provides that Section 5-35 of the Administrative Procedure Act [5 ILCS 100/5-35] does not apply to this rulemaking. Because this rulemaking is not subject to Section 5-35 of the APA, it is not subject to First Notice or to Second Notice review by JCAR.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None

7) Does this rulemaking replace any emergency rule currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? No

10) Are there any other rulemakings pending on this Part? No

11) Statement of Statewide Policy Objective: These proposed amendments do not create or enlarge a State mandate, as defined in Section 3(b) of the State Mandates Act [30 ILCS 805/3(b)].

12) Time, Place and Manner in which interested persons may comment on this rulemaking: The Board will accept written public comment on this proposal for a period of 45 days after the date of this publication. Comments should reference consolidated docket R20-3/R20-11 and be addressed to:

Don A. Brown, Clerk
Illinois Pollution Control Board
State of Illinois Center, Suite 11-500
100 W. Randolph St.

POLLUTION CONTROL BOARD

NOTICE OF PROPOSED AMENDMENTS

Chicago IL 60601

Please direct inquiries to the following person and reference consolidated docket R20-3/R20-11:

Michael J. McCambridge
Staff Attorney
Illinois Pollution Control Board
100 W. Randolph, 11-500
Chicago IL 60601

312/814-6924
michael.mccambridge@illinois.gov

Request copies of the Board's opinion and order at 312/814-3620, or download a copy from the Board's Website at pcb.illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities, and not-for-profit corporations affected: This rulemaking may affect those small businesses, small municipalities, and not-for-profit corporations disposing of industrial wastewaters into the sewage collection system of a publicly owned treatment works. These proposed amendments do not create or enlarge a State mandate, as defined in Section 3(b) of the State Mandates Act [30 ILCS 805/3(b)].

B) Reporting, bookkeeping or other procedures required for compliance: The existing rules and proposed amendments require extensive reporting, bookkeeping and other procedures, including the preparation of manifests and annual reports, waste analyses and maintenance of operating records. These proposed amendments do not create or enlarge a State mandate, as defined in Section 3(b) of the State Mandates Act [30 ILCS 805/3(b)].

C) Types of professional skills necessary for compliance: Compliance with the existing rules and proposed amendments may require the services of an attorney, certified public accountant, chemist and registered professional engineer. These proposed amendments do not create or enlarge a State mandate, as defined in Section 3(b) of the State Mandates Act [30 ILCS 805/3(b)].

14) Small Business Impact Analysis: Sections 1-5(c) and 5-30 of the Administrative Procedure Act [5 ILCS 100/1-5(c) and 5-30] provide that small business impact analysis and related requirements under Section 5-30 do not apply to this type of identical-in-substance rulemaking.

15) Regulatory Agenda on which this rulemaking was summarized: January 2020

The full text of the Proposed Amendments begins on the next page:

1ST NOTICE VERSION

JCAR350726-2009732r01

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE G: WASTE DISPOSAL
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER c: HAZARDOUS WASTE OPERATING REQUIREMENTS

PART 726
STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTE AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

SUBPART A: GENERAL

Section

726.102 Electronic Reporting

SUBPART C: RECYCLABLE MATERIALS USED IN A MANNER CONSTITUTING DISPOSAL

Section

726.120 Applicability

726.121 Standards Applicable to Generators and Transporters of Materials Used in a Manner that Constitutes Disposal

726.122 Standards Applicable to Storers, Who Are Not the Ultimate Users, of Materials that Are To Be Used in a manner that Constitutes Disposal

726.123 Standards Applicable to Users of Materials that Are Used in a Manner that Constitutes Disposal

SUBPART D: HAZARDOUS WASTE BURNED FOR ENERGY RECOVERY

Section

726.130 Applicability (Repealed)

726.131 Prohibitions (Repealed)

726.132 Standards applicable to generators of hazardous waste fuel (Repealed)

726.133 Standards applicable to transporters of hazardous waste fuel (Repealed)

726.134 Standards applicable to marketers of hazardous waste fuel (Repealed)

726.135 Standards applicable to burners of hazardous waste fuel (Repealed)

726.136 Conditional exemption for spent materials and by-products exhibiting a characteristic of hazardous waste (Repealed)

SUBPART E: USED OIL BURNED FOR ENERGY RECOVERY

Section

726.140 Applicability (Repealed)

726.141 Prohibitions (Repealed)

726.305	Standards Applicable to the Storage of Solid Waste Military Munitions
726.306	Standards Applicable to the Treatment and Disposal of Waste Military Munitions

SUBPART N: CONDITIONAL EXEMPTION FOR LOW-LEVEL MIXED WASTE STORAGE, TREATMENT, TRANSPORTATION AND DISPOSAL

Section	
726.310	Definitions
726.320	Storage and Treatment Conditional Exemption
726.325	Wastes Eligible for a Storage and Treatment Conditional Exemption for Low-Level Mixed Waste
726.330	Conditions to Qualify for and Maintain a Storage and Treatment Conditional Exemption
726.335	Treatment Allowed by a Storage and Treatment Conditional Exemption
726.340	Loss of a Storage and Treatment Conditional Exemption and Required Action
726.345	Reclaiming a Lost Storage and Treatment Conditional Exemption
726.350	Recordkeeping for a Storage and Treatment Conditional Exemption
726.355	Waste No Longer Eligible for a Storage and Treatment Conditional Exemption
726.360	Applicability of Closure Requirements to Storage Units
726.405	Transportation and Disposal Conditional Exemption
726.410	Wastes Eligible for a Transportation and Disposal Conditional Exemption
726.415	Conditions to Qualify for and Maintain a Transportation and Disposal Conditional Exemption
726.420	Treatment Standards for Eligible Waste
726.425	Applicability of the Manifest and Transportation Condition
726.430	Effectiveness of a Transportation and Disposal Exemption
726.435	Disposal of Exempted Waste
726.440	Containers Used for Disposal of Exempted Waste
726.445	Notification
726.450	Recordkeeping for a Transportation and Disposal Conditional Exemption
726.455	Loss of a Transportation and Disposal Conditional Exemption and Required Action
726.460	Reclaiming a Lost Transportation and Disposal Conditional Exemption

SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS

Section	
726.600	Definitions
726.601	Applicability
726.602	Standards for Non-Creditable Hazardous Waste Pharmaceuticals
726.603	Standards for Potentially Creditable Hazardous Waste Pharmaceuticals
726.604	Very Small Quantity Generators
726.605	Prohibition Against Sewering

726.606	Conditional Exemptions for Controlled Substances and Household Hazardous Waste Pharmaceuticals
726.607	Residues in Empty Containers
726.608	Shipping from a Healthcare Facility or Reverse Distributor
726.609	Shipping to a Reverse Distributor
726.610	Standards for Reverse Distributors

726.APPENDIX A	Tier I and Tier II Feed Rate and Emissions Screening Limits for Metals
726.APPENDIX B	Tier I Feed Rate Screening Limits for Total Chlorine
726.APPENDIX C	Tier II Emission Rate Screening Limits for Free Chlorine and Hydrogen Chloride
726.APPENDIX D	Reference Air Concentrations
726.APPENDIX E	Risk-Specific Doses
726.APPENDIX F	Stack Plume Rise
726.APPENDIX G	Health-Based Limits for Exclusion of Waste-Derived Residues
726.APPENDIX H	Potential PICs for Determination of Exclusion of Waste-Derived Residues
726.APPENDIX I	Methods Manual for Compliance with BIF Regulations
726.APPENDIX J	Guideline on Air Quality Models (Repealed)
726.APPENDIX K	Lead-Bearing Materials that May be Processed in Exempt Lead Smelters
726.APPENDIX L	Nickel or Chromium-Bearing Materials that May Be Processed in Exempt Nickel-Chromium Recovery Furnaces
726.APPENDIX M	Mercury-Bearing Wastes that May Be Processed in Exempt Mercury Recovery Units
726.TABLE A	Exempt Quantities for Small Quantity Burner Exemption

AUTHORITY: Implementing Sections 7.2 and 22.4 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/7.2, 22.4 and 27].

SOURCE: Adopted in R85-22 at 10 Ill. Reg. 1162, effective January 2, 1986; amended in R86-1 at 10 Ill. Reg. 14156, effective August 12, 1986; amended in R87-26 at 12 Ill. Reg. 2900, effective January 15, 1988; amended in R89-1 at 13 Ill. Reg. 18606, effective November 13, 1989; amended in R90-2 at 14 Ill. Reg. 14533, effective August 22, 1990; amended in R90-11 at 15 Ill. Reg. 9727, effective June 17, 1991; amended in R91-13 at 16 Ill. Reg. 9858, effective June 9, 1992; amended in R92-10 at 17 Ill. Reg. 5865, effective March 26, 1993; amended in R93-4 at 17 Ill. Reg. 20904, effective November 22, 1993; amended in R94-7 at 18 Ill. Reg. 12500, effective July 29, 1994; amended in R95-4/R95-6 at 19 Ill. Reg. 10006, effective June 27, 1995; amended in R95-20 at 20 Ill. Reg. 11263, effective August 1, 1996; amended in R96-10/R97-3/R97-5 at 22 Ill. Reg. 754, effective December 16, 1997; amended in R97-21/R98-3/R98-5 at 22 Ill. Reg. 18042, effective September 28, 1998; amended in R99-15 at 23 Ill. Reg. 9482, effective July 26, 1999; amended in R00-13 at 24 Ill. Reg. 9853, effective June 20, 2000;

amended in R02-1/R02-12/R02-17 at 26 Ill. Reg. 6667, effective April 22, 2002; amended in R03-7 at 27 Ill. Reg. 4200, effective February 14, 2003; amended in R03-18 at 27 Ill. Reg. 12916, effective July 17, 2003; amended in R06-5/R06-6/R06-7 at 30 Ill. Reg. 3700, effective February 23, 2006; amended in R06-16/R06-17/R06-18 at 31 Ill. Reg. 1096, effective December 20, 2006; amended in R07-5/R07-14 at 32 Ill. Reg. 12741, effective July 14, 2008; amended in R11-2/R11-16 at 35 Ill. Reg. 18117, effective October 14, 2011; amended in R13-5 at 37 Ill. Reg. 3249, effective March 4, 2013; amended in R13-15 at 37 Ill. Reg. 17888, effective October 24, 2013; amended in R16-7 at 40 Ill. Reg. 11955, effective August 9, 2016; amended in R17-14/R17-15/R18-12/R18-31 at 42 Ill. Reg. 23023, effective November 19, 2018; amended in R20-3/R20-11 at 44 Ill. Reg. _____, effective _____.

SUBPART G: SPENT LEAD-ACID BATTERIES BEING RECLAIMED

Section 726.180 Applicability and Requirements

a) Extent of Exemption for Spent Lead-Acid Batteries from Hazardous Waste Management Requirements. If an owner or operator generates, collects, transports, stores, or regenerates lead-acid batteries for reclamation purposes, the owner or operator may be exempt from certain hazardous waste management requirements. Subsections (a)(1) though (a)(5) indicate which requirements apply to the owner or operator. Alternatively, the owner or operator may choose to manage its spent lead-acid batteries under the "Universal Waste" rule in 35 Ill. Adm. Code 733.

1) If the spent lead-acid batteries will be reclaimed through regeneration (such as by electrolyte replacement), the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, 722 through 726 (except for 35 Ill. Adm. Code 722.111), and 728 and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111.

2) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator generates, collects, or transports the batteries, the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

3) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator stores the batteries, but the owner or operator is not the reclaimer, the owner or operator is exempt from the

requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

4) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator stores the batteries before the owner or operator reclaims them, the owner or operator must comply with the requirements of Section 726.180(b) and other requirements described in that subsection, and the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

5) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator does not store the batteries before the owner or operator reclaims them, the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), and the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

6) If the spent lead-acid batteries will be reclaimed through regeneration or any other means, and the batteries are exported for reclamation in a foreign country, the owner or operator is exempt from 35 Ill. Adm. Code 702, 703, 722 (except for 35 Ill. Adm. Code 722.111, 722.112 and Subpart H of 35 Ill. Adm. Code 722), 723 through 726, and 728, and the notification requirements at section 3010 of RCRA (42 USC 6930). The owner or operator is subject to the requirements of 35 Ill. Adm. Code 721, 722.111, and 722.112 and Subpart H of 35 Ill. Adm. Code 722.

7) If the spent lead-acid batteries will be reclaimed through regeneration or any other means, the person that transports the batteries in the United States to export them for reclamation in a foreign country (the transporter) is exempt from 35 Ill. Adm. Code 702, 703, 723 through 726, and 728, and the notification requirements at section 3010 of RCRA (42 USC 6930). The transporter must comply with the applicable requirements in Subpart H of 35 Ill. Adm. Code 722.

8) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country and stores them but is not the reclaimer, the person is exempt from

35 Ill. Adm. Code 722 (except for 35 Ill. Adm. Code 722.111 and 722.112 and Subpart H of 35 Ill. Adm. Code 722), 702, 703, 723, 724, 725, and 726, and the notification requirements at section 3010 of RCRA (42 USC 6930). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

9) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country and stores them before reclaiming them, the person must comply with 35 Ill. Adm. Code 726.180(b) and as appropriate other regulatory provisions described in 35 Ill. Adm. Code 726.180(b). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

10) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country does not store them before reclaiming ~~reclaiming~~ them, the person is exempt from 35 Ill. Adm. Code 702, 703, 722 (except for 35 Ill. Adm. Code 722.111 and 722.112 and Subpart H of 35 Ill. Adm. Code 722), 723, 724, 725, and 726 and the notification requirements at section 3010 of RCRA (42 USC 6930). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

b) Exemption for Spent Lead-Acid Batteries Stored before Reclamation Other Than Through Regeneration. The requirements of this subsection (b) apply to an owner or operator that stores spent lead-acid batteries before it reclaims them, where the owner or operator does not reclaim them through regeneration. The requirements are slightly different depending on the owner's or operator's RCRA permit status.

1) For an interim status facility, the owner or operator must comply with the following requirements:

A) The notification requirements under Section 3010 of RCRA (42 USC 6930);

B) All applicable provisions in Subpart A of 35 Ill. Adm. Code 725;

C) All applicable provisions in Subpart B of 35 Ill. Adm. Code 725, except 35 Ill. Adm. Code 725.113 (waste analysis);

D) All applicable provisions in Subparts C and D of 35 Ill. Adm. Code

725;

E) All applicable provisions in Subpart E of 35 Ill. Adm. Code 725, except 35 Ill. Adm. Code 725.171 and 725.172 (dealing with the use of the manifest and manifest discrepancies);

F) All applicable provisions in Subparts F through L of 35 Ill. Adm. Code 725;

G) All applicable provisions in 35 Ill. Adm. Code 702 and 703; and

H) All applicable provisions in 35 Ill. Adm. Code 727.

2) For a permitted facility, the following requirements:

A) The notification requirements under section 3010 of RCRA (42 USC 6930);

B) All applicable provisions in Subpart A of 35 Ill. Adm. Code 724;

C) All applicable provisions in Subpart B of 35 Ill. Adm. Code 724, except 35 Ill. Adm. Code 724.113 (waste analysis);

D) All applicable provisions in Subparts C and D of 35 Ill. Adm. Code 724;

E) All applicable provisions in Subpart E of 35 Ill. Adm. Code 724, except 35 Ill. Adm. Code 724.171 or 724.172 (dealing with the use of the manifest and manifest discrepancies);

F) All applicable provisions in Subparts F through L of 35 Ill. Adm. Code 724;

G) All applicable provisions in 35 Ill. Adm. Code 702 and 703; and

H) All applicable provisions in 35 Ill. Adm. Code 727.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART H: HAZARDOUS WASTE BURNED IN BOILERS AND INDUSTRIAL FURNACES

Section 726.202 Permit Standards for Burners

a) Applicability

1) General. An owner or operator of a BIF that burns hazardous waste and which does not operate under interim status must comply with the requirements of this Section and 35 Ill. Adm. Code 703.208 and 703.232, unless exempt pursuant to the small quantity burner exemption of Section 726.208.

2) Applicability of 35 Ill. Adm. Code 724 Standards. An owner or operator of a BIF that burns hazardous waste is subject to the following provisions of 35 Ill. Adm. Code 724, except as provided otherwise by this Subpart H:

A) In Subpart A (General), 35 Ill. Adm. Code 724.104;

B) In Subpart B (General facility standards), 35 Ill. Adm. Code 724.111 through 724.118;

C) In Subpart C (Preparedness and prevention), 35 Ill. Adm. Code 724.131 through 724.137;

D) In Subpart D (Contingency plan and emergency procedures), 35 Ill. Adm. Code 724.151 through 724.156;

E) In Subpart E (Manifest system, recordkeeping and reporting), the applicable provisions of 35 Ill. Adm. Code 724.171 through 724.177;

F) In Subpart F (Releases from Solid Waste Management Units), 35 Ill. Adm. Code 724.190 and 724.201;

G) In Subpart G (Closure and post-closure), 35 Ill. Adm. Code 724.211 through 724.215;

H) In Subpart H (Financial requirements), 35 Ill. Adm. Code 724.241, 724.242, 724.243, and 724.247 through 724.251, except that the State of Illinois and the federal government are exempt from the requirements of Subpart H of 35 Ill. Adm. Code 724; and

I) Subpart BB (Air emission standards for equipment leaks), except 35 Ill. Adm. Code 724.950(a).

b) Hazardous Waste Analysis

1) The owner or operator must provide an analysis of the hazardous waste that quantifies the concentration of any constituent identified in Appendix H of 35 Ill. Adm. Code 721 that is reasonably expected to be in the waste. Such constituents must be identified and quantified if present, at levels detectable by using appropriate analytical methods. The constituents listed in Appendix H of 35 Ill. Adm. Code 721 that are excluded from this analysis must be identified and the basis for their exclusion explained. This analysis must provide all information required by this Subpart H and 35 Ill. Adm. Code 703.208 and 703.232 and must enable the Agency to prescribe such permit conditions as are necessary to adequately protect human health and the environment. Such analysis must be included as a portion of the Part B permit application, or, for facilities operating under the interim status standards of this Subpart H, as a portion of the trial burn plan that may be submitted before the Part B application pursuant to provisions of 35 Ill. Adm. Code 703.232(g), as well as any other analysis required by the Agency. The owner or operator of a BIF not operating under the interim status standards must provide the information required by 35 Ill. Adm. Code 703.208 and 703.232 in the Part B application to the greatest extent possible.

2) Throughout normal operation, the owner or operator must conduct sampling and analysis as necessary to ensure that the hazardous waste, other fuels, and industrial furnace feedstocks fired into the BIF are within the physical and chemical composition limits specified in the permit.

c) Emissions Standards. An owner or operator must comply with emissions standards provided by Sections 726.204 through 726.207.

d) Permits

1) The owner or operator must burn only hazardous wastes specified in the facility permit and only under the operating conditions specified pursuant to subsection (e), except in approved trial burns under the conditions specified in 35 Ill. Adm. Code 703.232.

2) Hazardous wastes not specified in the permit must not be burned until operating conditions have been specified under a new permit or permit modification, as applicable. Operating requirements for new wastes must be based on either trial burn results or alternative data included with Part B of a permit application pursuant to 35 Ill. Adm. Code 703.208.

3) BIFs operating under the interim status standards of Section 726.203 are

permitted pursuant to procedures provided by 35 Ill. Adm. Code 703.232(g).

4) A permit for a new BIF (those BIFs not operating under the interim status standards) must establish appropriate conditions for each of the applicable requirements of this Section, including but not limited to allowable hazardous waste firing rates and operating conditions necessary to meet the requirements of subsection (e), in order to comply with the following standards:

A) For the period beginning with initial introduction of hazardous waste and ending with initiation of the trial burn, and only for the minimum time required to bring the device to a point of operational readiness to conduct a trial burn, not to exceed a duration of 720 hours operating time when burning hazardous waste, the operating requirements must be those most likely to ensure compliance with the emission standards of Sections 726.204 through 726.207, based on the Agency's engineering judgment. If the applicant is seeking a waiver from a trial burn to demonstrate conformance with a particular emission standard, the operating requirements during this initial period of operation must include those specified by the applicable provisions of Section 726.204, Section 726.205, Section 726.206, or Section 726.207. The Agency must extend the duration of this period for up to 720 additional hours when good cause for the extension is demonstrated by the applicant.

B) For the duration of the trial burn, the operating requirements must be sufficient to demonstrate compliance with the emissions standards of Sections 726.204 through 726.207 and must be in accordance with the approved trial burn plan;

C) For the period immediately following completion of the trial burn, and only for the minimum period sufficient to allow sample analysis, data computation, submission of the trial burn results by the applicant, review of the trial burn results, and modification of the facility permit by the Agency to reflect the trial burn results, the operating requirements must be those most likely to ensure compliance with the emission standards Sections 726.204 through 726.207 based on the Agency's engineering judgment.

D) For the remaining duration of the permit, the operating requirements must be those demonstrated in a trial burn or by

alternative data specified in 35 Ill. Adm. Code 703.208, as sufficient to ensure compliance with the emissions standards of Sections 726.204 through 726.207.

e) Operating Requirements

1) General. A BIF burning hazardous waste must be operated in accordance with the operating requirements specified in the permit at all times when there is hazardous waste in the unit.

2) Requirements to Ensure Compliance with the Organic Emissions Standards

A) DRE (destruction or removal efficiency) Standard. Operating conditions must be specified in either of the following ways: on a case-by-case basis for each hazardous waste burned, which conditions must be demonstrated (in a trial burn or by alternative data, as specified in 35 Ill. Adm. Code 703.208) to be sufficient to comply with the DRE performance standard of Section 726.204(a), or as special operating requirements provided by Section 726.204(a)(4) for the waiver of the DRE trial burn. When the DRE trial burn is not waived pursuant to Section 726.204(a)(4), each set of operating requirements must specify the composition of the hazardous waste (including acceptable variations in the physical and chemical properties of the hazardous waste that will not affect compliance with the DRE performance standard) to which the operating requirements apply. For each such hazardous waste, the permit must specify acceptable operating limits including, but not limited to, the following conditions, as appropriate:

i) Feed rate of hazardous waste and other fuels measured and specified as prescribed in subsection (e)(6);

ii) Minimum and maximum device production rate when producing normal product expressed in appropriate units, measured and specified as prescribed in subsection (e)(6);

iii) Appropriate controls of the hazardous waste firing system;

iv) Allowable variation in BIF system design or operating procedures;

v) Minimum combustion gas temperature measured at a

location indicative of combustion chamber temperature, measured, and specified as prescribed in subsection (e)(6);

vi) An appropriate indicator of combustion gas velocity, measured and specified as prescribed in subsection (e)(6), unless documentation is provided pursuant to 35 Ill. Adm. Code 703.232 demonstrating adequate combustion gas residence time; and

vii) Such other operating requirements as are necessary to ensure that the DRE performance standard of Section 726.204(a) is met.

B) CO and Hydrocarbon (HC) Standards. The permit must incorporate a CO limit and, as appropriate, a HC limit as provided by Section 726.204(b), (c), (d), (e), and (f). The permit limits must be specified as follows:

i) When complying with the CO standard of Section 726.204(b)(1), the permit limit is 100 ppmv;

ii) When complying with the alternative CO standard pursuant to Section 726.204(c), the permit limit for CO is based on the trial burn and is established as the average over all valid runs of the highest hourly rolling average CO level of each run; and, the permit limit for HC is 20 ppmv (as defined in Section 726.204(c)(1)), except as provided in Section 726.204(f); or

iii) When complying with the alternative HC limit for industrial furnaces pursuant to Section 726.204(f), the permit limit for HC and CO is the baseline level when hazardous waste is not burned as specified by that subsection.

C) Start-Up and Shut-Down. During start-up and shut-down of the BIF, hazardous waste (except waste fed solely as an ingredient under the Tier I (or adjusted Tier I) feed rate screening limits for metals and chloride/chlorine, and except low risk waste exempt from the trial burn requirements pursuant to Sections 726.204(a)(5), 726.205, 726.206, and 726.207) must not be fed into the device, unless the device is operating within the conditions of operation specified in the permit.

3) Requirements to Ensure Conformance with the Particulate Matter (PM) Standard

A) Except as provided in subsections (e)(3)(B) and (e)(3)(C), the permit must specify the following operating requirements to ensure conformance with the PM standard specified in Section 726.205:

i) Total ash feed rate to the device from hazardous waste, other fuels, and industrial furnace feedstocks, measured and specified as prescribed in subsection (e)(6);

ii) Maximum device production rate when producing normal product expressed in appropriate units, and measured and specified as prescribed in subsection (e)(6);

iii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any air pollution control system (APCS);

iv) Allowable variation in BIF system design including any APCS or operating procedures; and

v) Such other operating requirements as are necessary to ensure that the PM standard in Section 726.205(a) is met.

B) Permit conditions to ensure conformance with the PM standard must not be provided for facilities exempt from the PM standard pursuant to Section 726.205(b);

C) For cement kilns and light-weight aggregate kilns, permit conditions to ensure compliance with the PM standard must not limit the ash content of hazardous waste or other feed materials.

4) Requirements to Ensure Conformance with the Metals Emissions Standard

A) For conformance with the Tier I (or adjusted Tier I) metals feed rate screening limits of Section 726.206(b) or (e), the permit must specify the following operating requirements:

i) Total feed rate of each metal in hazardous waste, other fuels and industrial furnace feedstocks measured and specified pursuant to provisions of subsection (e)(6);

ii) Total feed rate of hazardous waste measured and specified as prescribed in subsection (e)(6); and

iii) A sampling and metals analysis program for the hazardous waste, other fuels and industrial furnace feedstocks;

B) For conformance with the Tier II metals emission rate screening limits pursuant to Section 726.206(c) and the Tier III metals controls pursuant to Section 726.206(d), the permit must specify the following operating requirements:

i) Maximum emission rate for each metal specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste and pumpable hazardous waste, each measured and specified as prescribed in subsection (e)(6)(A);

iii) Feed rate of each metal in the following feedstreams, measured and specified as prescribed in subsections (e)(6): total feed streams; total hazardous waste feed; and total pumpable hazardous waste feed;

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(4)(ii)(C)(*1*) and (e)(4)(ii)(C)(*2*) into this subsection (e)(4)(B)(iii) to comport with Illinois Administrative Code codification requirements.

iv) Total feed rate of chlorine and chloride in total feed streams measured and specified as prescribed in subsection (e)(6);

v) Maximum combustion gas temperature measured at a location indicative of combustion chamber temperature, and measured and specified as prescribed in subsection (e)(6);

vi) Maximum flue gas temperature at the inlet to the PM APCS measured and specified as prescribed in subsection (e)(6);

vii) Maximum device production rate when producing normal product expressed in appropriate units and measured and specified as prescribed in subsection (e)(6);

viii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

ix) Allowable variation in BIF system design including any APCS or operating procedures; and

x) Such other operating requirements as are necessary to ensure that the metals standards pursuant to Section 726.206(c) or (d) are met.

C) For conformance with an alternative implementation approach approved by the Agency pursuant to Section 726.206(f), the permit must specify the following operating requirements:

i) Maximum emission rate for each metal specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste and pumpable hazardous waste, each measured and specified as prescribed in subsection (e)(6)(A);

iii) Feed rate of each metal in the following feedstreams, measured and specified as prescribed in subsection (e)(6): total hazardous waste feed; and total pumpable hazardous waste feed;

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(4)(iii)(C)(*1*) and (e)(4)(iii)(C)(*2*) into this subsection (e)(4)(C)(iii) to comport with Illinois Administrative Code codification requirements.

iv) Total feed rate of chlorine and chloride in total feed streams measured and specified prescribed in subsection (e)(6);

v) Maximum combustion gas temperature measured at a location indicative of combustion chamber temperature, and measured and specified as prescribed in subsection (e)(6);

vi) Maximum flue gas temperature at the inlet to the PM APCS measured and specified as prescribed in subsection (e)(6);

vii) Maximum device production rate when producing normal product expressed in appropriate units and measured and specified as prescribed in subsection (e)(6);

viii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

ix) Allowable variation in BIF system design including any APCS or operating procedures; and

x) Such other operating requirements as are necessary to ensure that the metals standards pursuant to Section 726.206(c) or (d) are met.

5) Requirements to Ensure Conformance with the HCl and Chlorine Gas Standards

A) For conformance with the Tier I total chlorine and chloride feed rate screening limits of Section 726.207(b)(1), the permit must specify the following operating requirements:

i) Feed rate of total chlorine and chloride in hazardous waste, other fuels and industrial furnace feedstocks measured and specified as prescribed in subsection (e)(6);

ii) Feed rate of total hazardous waste measured and specified as prescribed in subsection (e)(6); and

iii) A sampling and analysis program for total chlorine and chloride for the hazardous waste, other fuels and industrial furnace feedstocks;

B) For conformance with the Tier II HCl and chlorine gas emission rate screening limits pursuant to Section 726.207(b)(2) and the Tier III HCl and chlorine gas controls pursuant to Section 726.207(c), the permit must specify the following operating requirements:

i) Maximum emission rate for HCl and for chlorine gas specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste measured and specified as prescribed in subsection (e)(6);

iii) Total feed rate of chlorine and chloride in total feed streams, measured and specified as prescribed in subsection (e)(6);

iv) Maximum device production rate when producing normal product expressed in appropriate units, measured and specified as prescribed in subsection (e)(6);

v) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

vi) Allowable variation in BIF system design including any APCS or operating procedures; and

vii) Such other operating requirements as are necessary to ensure that the HCl and chlorine gas standards pursuant to Section 726.207(b)(2) or (c) are met.

6) Measuring Parameters and Establishing Limits Based on Trial Burn Data

A) General Requirements. As specified in subsections (e)(2) through (e)(5), each operating parameter must be measured, and permit limits on the parameter must be established, according to either of the following procedures:

i) Instantaneous Limits. A parameter is measured and recorded on an instantaneous basis (i.e., the value that occurs at any time) and the permit limit specified as the time-weighted average during all valid runs of the trial burn; or

ii) Hourly Rolling Average. The limit for a parameter must be established and continuously monitored on an hourly rolling average basis, as defined in Section 726.200(i). The permit limit for the parameter must be established based on trial burn data as the average over all valid test runs of the highest hourly rolling average value for each run.

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(6)(i)(B)(*1*) and (e)(6)(i)(B)(*2*) into this subsection (e)(6)(A)(ii) and moved the text of 40 CFR 266.102(e)(6)(i)(B)(*1*)(*i*) and (e)(6)(i)(B)(*1*)(*ii*) to appear as definitions of "continuous monitor" and "hourly rolling

average", respectively, in Section 726.200(i) to comport with Illinois Administrative Code codification requirements.

B) Rolling Average Limits for Carcinogenic Metals and Lead. Feed rate limits for the carcinogenic metals (as defined in Section 726.200(i)) and lead must be established either on an hourly rolling average basis, as prescribed by subsection (e)(6)(A), or on (up to) a 24 hour rolling average basis. If the owner or operator elects to use an average period from 2 to 24 hours, the following requirements apply:

i) The feed rate of each metal must be limited at any time to ten times the feed rate that would be allowed on an hourly rolling average basis;

ii) The continuous monitor must meet the specifications of "continuous monitor", "rolling average for the selected averaging period", and "one hour block average" as defined in Section 726.200(i); and

BOARD NOTE: The Board has moved the text of 40 CFR 266.102(e)(6)(ii)(B)(*1*) and (e)(6)(ii)(B)(*2*) to appear as definitions in Section 726.200(i) to comport with Illinois Administrative Code codification requirements.

iii) The permit limit for the feed rate of each metal must be established based on trial burn data as the average over all valid test runs of the highest hourly rolling average feed rate for each run.

C) Feed Rate Limits for Metals, Total Chlorine and Chloride, and Ash. Feed rate limits for metals, total chlorine and chloride, and ash are established and monitored by knowing the concentration of the substance (i.e., metals, chloride/chlorine and ash) in each feedstream and the flow rate of the feedstream. To monitor the feed rate of these substances, the flow rate of each feedstream must be monitored pursuant to the continuous monitoring requirements of subsections (e)(6)(A) and (e)(6)(B).

D) Conducting~~Conduct of~~ Trial Burn Testing~~.~~

i) If compliance with all applicable emissions standards of

Sections 726.204 through 726.207 is not demonstrated simultaneously during a set of test runs, the operating conditions of additional test runs required to demonstrate compliance with remaining emissions standards must be as close as possible to the original operating conditions.

ii) Prior to obtaining test data for purposes of demonstrating compliance with the emissions standards of Sections 726.204 through 726.207 or establishing limits on operating parameters pursuant to this Section, the unit must operate under trial burn conditions for a sufficient period to reach steady-state operations. However, industrial furnaces that recycle collected PM back into the furnace and that comply with an alternative implementation approach for metals pursuant to Section 726.206(f) need not reach steady state conditions with respect to the flow of metals in the system prior to beginning compliance testing for metals emissions.

iii) Trial burn data on the level of an operating parameter for which a limit must be established in the permit must be obtained during emissions sampling for the pollutants (i.e., metals, PM, HCl/chlorine gas, organic compounds) for which the parameter must be established as specified by this subsection (e).

7) General Requirements

A) Fugitive Emissions. Fugitive emissions must be controlled in one of the following ways:

i) By keeping the combustion zone totally sealed against fugitive emissions;

ii) By maintaining the combustion zone pressure lower than atmospheric pressure; or

iii) By an alternative means of control demonstrated (with Part B of the permit application) to provide fugitive emissions control equivalent to maintenance of combustion zone pressure lower than atmospheric pressure.

B) Automatic Waste Feed Cutoff. A BIF must be operated with a

functioning system that automatically cuts off the hazardous waste feed when operating conditions deviate from those established pursuant to this Section. In addition, the following requirements apply:

i) The permit limit for (the indicator of) minimum combustion chamber temperature must be maintained while hazardous waste or hazardous waste residues remain in the combustion chamber;

ii) Exhaust gases must be ducted to the APCS operated in accordance with the permit requirements while hazardous waste or hazardous waste residues remain in the combustion chamber; and

iii) Operating parameters for which permit limits are established must continue to be monitored during the cutoff, and the hazardous waste feed must not be restarted until the levels of those parameters comply with the permit limits. For parameters that are monitored on an instantaneous basis, the Agency must establish a minimum period of time after a waste feed cutoff during which the parameter must not exceed the permit limit before the hazardous waste feed is restarted.

C) Changes. A BIF must cease burning hazardous waste when combustion properties or feed rates of the hazardous waste, other fuels or industrial furnace feedstocks, or the BIF design or operating conditions deviate from the limits as specified in the permit.

8) Monitoring and Inspections

A) The owner or operator must monitor and record the following, at a minimum, while burning hazardous waste:

i) If specified by the permit, feed rates and composition of hazardous waste, other fuels, and industrial furnace feedstocks and feed rates of ash, metals, and total chlorine and chloride;

ii) If specified by the permit, CO, HCs, and oxygen on a continuous basis at a common point in the BIF downstream

of the combustion zone and prior to release of stack gases to the atmosphere in accordance with operating requirements specified in subsection (e)(2)(B). CO, HC, and oxygen monitors must be installed, operated, and maintained in accordance with methods specified in Appendix I; and

iii) Upon the request of the Agency, sampling and analysis of the hazardous waste (and other fuels and industrial furnace feedstocks as appropriate), residues, and exhaust emissions must be conducted to verify that the operating requirements established in the permit achieve the applicable standards of Sections 726.204, 726.205, 726.206, and 726.207.

B) All monitors must record data in units corresponding to the permit limit unless otherwise specified in the permit.

C) The BIF and associated equipment (pumps, valves, pipes, fuel storage tanks, etc.) must be subjected to thorough visual inspection when it contains hazardous waste, at least daily for leaks, spills, fugitive emissions, and signs of tampering.

D) The automatic hazardous waste feed cutoff system and associated alarms must be tested at least once every seven days when hazardous waste is burned to verify operability, unless the applicant demonstrates to the Agency that weekly inspections will unduly restrict or upset operations and that less frequent inspections will be adequate. At a minimum, operational testing must be conducted at least once every 30 days.

E) These monitoring and inspection data must be recorded and the records must be placed in the operating record required by 35 Ill. Adm. Code 724.173.

9) Direct Transfer to the Burner. If hazardous waste is directly transferred from a transport vehicle to a BIF without the use of a storage unit, the owner and operator must comply with Section 726.211.

10) Recordkeeping. The owner or operator must maintain in the operating record of the facility all information and data required by this Section for five years.

11) Closure. At closure, the owner or operator must remove all hazardous

waste and hazardous waste residues (including, but not limited to, ash, scrubber waters, and scrubber sludges) from the BIF.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART M: MILITARY MUNITIONS

Section 726.305 Standards Applicable to the Storage of Solid Waste Military Munitions

a) Criteria for Hazardous Waste Regulation of Waste Non-Chemical Military Munitions in Storage

1) Waste military munitions in storage that exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721 are listed or identified as a hazardous waste (and thus are subject to regulation pursuant to 35 Ill. Adm. Code 702, 703, 705, 720 through 728, 733, 738, and 739), unless all the following conditions are met:

A) The waste military munitions are not chemical agents or chemical munitions;

B) The waste military munitions must be subject to the jurisdiction of the Department of Defense Explosives Safety Board (DDESB);

C) The waste military munitions must be stored in accordance with the DDESB storage standards applicable to waste military munitions;

D) Within 90 days of when a storage unit is first used to store waste military munitions, the owner or operator must notify the Agency of the location of any waste storage unit used to store waste military munitions for which the conditional exemption in subsection (a)(1) is claimed;

E) The owner or operator must provide oral notice to the Agency within 24 hours from the time the owner or operator becomes aware of any loss or theft of the waste military munitions, or any failure to meet a condition of subsection (a)(1) that may endanger health or the environment. In addition, a written submission describing the circumstances must be provided within five days from the time the owner or operator becomes aware of any loss or theft of the waste military munitions or any failure to meet a

condition of subsection (a)(1);

F) The owner or operator must inventory the waste military munitions at least annually, must inspect the waste military munitions at least quarterly for compliance with the conditions of subsection (a)(1), and must maintain records of the findings of these inventories and inspections for at least three years; and

G) Access to the stored waste military munitions must be limited to appropriately trained and authorized personnel.

2) The conditional exemption in subsection (a)(1) from regulation as hazardous waste must apply only to the storage of non-chemical waste military munitions. It does not affect the regulatory status of waste military munitions as hazardous wastes with regard to transportation, treatment or disposal.

3) The conditional exemption in subsection (a)(1) applies only so long as all of the conditions in subsection (a)(1) are met.

b) Notice of Termination of Waste Storage. The owner or operator must notify the Agency when a storage unit identified in subsection (a)(1)(D) will no longer be used to store waste military munitions.

c) Reinstatement of Conditional Exemption

1) If any waste military munition loses its conditional exemption pursuant to subsection (a)(1), an application may be filed with the Agency for reinstatement of the conditional exemption from hazardous waste storage regulation with respect to such munition as soon as the munition is returned to compliance with the conditions of subsection (a)(1).

2) If the Agency finds that reinstatement of the conditional exemption is appropriate, it must reinstate the conditional exemption of subsection (a)(1) in writing. The Agency's decision to reinstate or not to reinstate the conditional exemption must be based on two considerations~~consideritions~~: first, the nature of the risks to human health and the environment posed by the waste; and second, either the owner's or operator's provision of a satisfactory explanation of the circumstances of the violation or any demonstration that the violations are not likely to recur. If the Agency denies an application, it must transmit to the applicant specific, detailed statements in writing as to the reasons it denied the application. In reinstating the conditional exemption pursuant to subsection (a)(1), the

Agency may specify additional conditions as are necessary to ensure and document proper storage to adequately protect human health and the environment.

3) The Agency may terminate a conditional exemption reinstated by default pursuant to subsection (c)(2) in writing if it finds that reinstatement is inappropriate based on its consideration of the factors set forth in subsection (c)(2). If the Agency terminates a reinstated exemption, it must transmit to the applicant specific, detailed statements in writing as to the reasons it terminated the reinstated exemption.

4) The applicant pursuant to this subsection (c) may appeal the Agency's determination to deny the reinstatement, to grant the reinstatement with conditions, or to terminate a reinstatement before the Board pursuant to Section 40 of the Act.

d) Waste Chemical Munitions

1) Waste military munitions are subject to the applicable regulatory requirements of RCRA subtitle C if the munitions satisfy two conditions: first, they are chemical agents or chemical munitions; and second, they exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721.

2) Waste military munitions are not subject to the storage prohibition in RCRA section 3004(j), codified at 35 Ill. Adm. Code 728.150, if the munitions satisfy two conditions: first, they are chemical agents or chemical munitions; and second, they exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721.

e) Amendments to DDESB Storage Standards. The DDESB storage standards applicable to waste military munitions, referenced in subsection (a)(1)(C), are DOD 6055.9-STD ("DOD Ammunition and Explosive Safety Standards"), in effect on November 8, 1995, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding federal provision 40 CFR 266.205(e), as added at 62 Fed. Reg. 6656 (Feb. 12, 1997), further provides as follows: "Any amendments to the DDESB storage standards must become effective for purposes of paragraph (a)(1) of this section on the date the Department of Defense publishes notice in the Federal Register that the DDESB standards referenced in paragraph (a)(1) of this section have been amended." Section 5-75 of the Illinois

Administrative Procedure Act [5 ILCS 100/5-75] prohibits the incorporation of later amendments and editions by reference. For this reason, interested members of the regulated community will need to notify the Board of any amendments of these references before those amendments can become effective under Illinois law.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS

Section 726.600 Definitions

The following definitions apply to this Subpart P:

"Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with Section 726.610(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

"Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code 721.102, and that exhibits one or more characteristics identified in Subpart C of 35 Ill. Adm. Code 721 or that is listed in Subpart D of 35 Ill. Adm. Code 721. A pharmaceutical is not a solid waste, as defined in 35 Ill. Adm. Code 721.102, and therefore is not a hazardous waste pharmaceutical, if it is legitimately used or reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in 35 Ill. Adm. Code 721.102, and therefore is not a hazardous waste pharmaceutical, if there is a reasonable expectation of its being legitimately used or reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

"Healthcare facility" means any person that is lawfully authorized to do the following:

Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care and counseling, service, assessment, or procedure with respect to the physical or mental condition or functional status of a human or animal or affecting the structure or function of the human or animal body; or

Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes wholesale distributors, third-

party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical treatment centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

"Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code 721.102, but that is excluded from being a hazardous waste under 35 Ill. Adm. Code 721.104(b)(1).

"Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals, to one or more individuals at the facility. This definition includes hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

"Non-creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used or reused or reclaimed. This includes investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and cleanup material from the spills of pharmaceuticals.

"Non-hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code 721.102; is not listed in Subpart D of 35 Ill. Adm. Code 721; and does not exhibit a characteristic identified in Subpart C of 35 Ill. Adm. Code 721.

"Non-pharmaceutical hazardous waste" means a solid waste, as defined in 35 Ill. Adm. Code 721.102, that is listed in Subpart D of 35 Ill. Adm. Code 721, exhibits one or more characteristics identified in Subpart C of 35 Ill. Adm. Code 721, but is not a pharmaceutical, as defined in this Section.

"Pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or

vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes dietary supplements, as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 USC 321(ff)), incorporated by reference in 35 Ill. Adm. Code 720.111; prescription drugs, as defined in 21 CFR 203.3(y), incorporated by reference in 35 Ill. Adm. Code 720.111; over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in nonempty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

"Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and of which the following is true:

It is in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

It is undispensed; and

It is unexpired or less than one year past its expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals, including over-the-counter drugs, homeopathic drugs, and dietary supplements.

"Reverse distributor" means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.601 Applicability

a) A healthcare facility that is a VSQG when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 35 Ill. Adm. Code 722.114 and is not subject to this Subpart P, except for Sections 726.605 and 726.607 and the optional provisions of Section 726.604.

b) A healthcare facility that is a VSQG when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with Section 726.601(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with 35 Ill. Adm. Code 722.114 and the optional provisions of Section 726.604.

c) A healthcare facility or reverse distributor remains subject to all applicable requirements in 35 Ill. Adm. Code 722 through 725 with respect to the management of its non-pharmaceutical hazardous waste.

d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to the following in lieu of 35 Ill. Adm. Code 722 through 725:

1) Sections 726.602 and 726.605 through 726.608 with respect to the management of the following:

A) Non-creditable hazardous waste pharmaceuticals; and

B) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

2) Sections 726.602(a), 726.603, 726.605 through 726.607, and 726.609 with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and that are destined for a reverse distributor.

e) A reverse distributor is subject to Sections 726.605 through 726.610, in lieu of 35 Ill. Adm. Code 722 through 725, with respect to the management of hazardous waste pharmaceuticals.

f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this Subpart P. Other generators are subject to 35 Ill. Adm. Code 722 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

g) The following are not subject to 35 Ill. Adm. Code 720 through 733, except as otherwise specified:

1) Pharmaceuticals that are not solid waste, as defined by 35 Ill. Adm. Code 721.102, because they are legitimately used or reused (e.g., lawfully donated for their intended purpose) or reclaimed.

2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by 35 Ill. Adm. Code 721.102, because there is a reasonable expectation of their being legitimately used or reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with subpart C of 21 CFR 7. This Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR 1115. This Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

5) Pharmaceuticals stored according to a preservation order or during an investigation or judicial proceeding, until after the preservation order, investigation, or judicial proceeding has concluded or a decision is made to discard the pharmaceuticals.

6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR 312. This Subpart P applies to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

7) Household waste pharmaceuticals, including those that have been collected by a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, provided the authorized collector complies with the conditional exemption in Section 726.606(a)(2) and (b).

BOARD NOTE: The Drug Enforcement Administration regulations define "collector" in the second segment of the definition of "collection" in 21 CFR 1300.01. The authorized status of the collector is part of the definition.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.602 Standards for Non-Creditable Hazardous Waste Pharmaceuticals

a) Notification and Withdrawal from this Subpart P for Healthcare Facilities Managing Hazardous Waste Pharmaceuticals

1) Notification. A healthcare facility must notify the Agency, using Notification of RCRA Subtitle C Activities (Site Identification Form) (USEPA Form 8700-12), that it is a healthcare facility operating under this Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using the Site Identification Form) for each site or USEPA identification number.

A) A healthcare facility that already has a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or, if not required to submit an annual report, within 60 days after becoming subject to this Subpart P.

B) A healthcare facility that does not have a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or if not required to submit an annual report, within 60 days after becoming subject to this Subpart P.

C) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this Subpart P.

BOARD NOTE: Corresponding 40 CFR 266.602(a)(1) requires biennial reporting. The Board has required annual reporting, since Section 20.1 of the Act requires the Agency to assemble annual reports, and only annual facility activity reports will enable the Agency to fulfill this mandate.

2) Withdrawal. A healthcare facility that operated under this Subpart P but is no longer subject to this Subpart P, because it is a VSQG under 35 Ill. Adm. Code 722.114, and that elects to withdraw from this Subpart P, must notify the appropriate agency using USEPA Form 8700-12 that it is no longer operating under this Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous

Waste) of USEPA Form 8700-12 with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using USEPA Form 8700-12) for each USEPA identification number.

A) A healthcare facility must submit USEPA Form 8700-12 notifying that it is withdrawing from this Subpart P before it begins operating under the conditional exemption of 35 Ill. Adm. Code 722.114.

B) A healthcare facility must keep a copy of its withdrawal on file for three years after the date of signature on the notification of its withdrawal.

b) Training of Personnel Managing Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must ensure that all personnel managing non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

c) Hazardous Waste Determination for Non-Creditable Pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in Subpart D of 35 Ill. Adm. Code 721 or is listed in Subpart D of 35 Ill. Adm. Code 721) in order to determine whether the waste is subject to this Subpart P. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this Subpart P.

d) Standards for Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals, must manage the container so that it does not have the potential to do any of the following:

A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

D) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

E) Through other like means threaten human health or the environment.

3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to their contents.

4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and nonhazardous non-creditable waste pharmaceuticals in the same container, except that the healthcare facility must accumulate non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) in separate containers and label the containers with all applicable USEPA hazardous waste numbers.

e) Labeling Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals".

f) Maximum Accumulation Time for Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the facility has accumulated the non-creditable hazardous waste pharmaceuticals, starting from the date it first becomes a waste. A

healthcare facility may make this demonstration by any of the following methods:

A) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date when the non-creditable hazardous waste pharmaceuticals became a waste;

B) Maintaining an inventory system that identifies the date when the accumulated non-creditable hazardous waste pharmaceuticals first became a waste;

C) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date when any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

g) Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with 35 Ill. Adm. Code 728.107(a) requirements, except that it is not required to identify the USEPA hazardous waste numbers on the land disposal restrictions notification.

h) Procedures for Healthcare Facilities for Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with subsections (d) and (e). Upon receipt of the returned shipment, the healthcare facility must do the following:

1) Sign the applicable of the following:

A) Item 18c (Signature of Alternate Facility (or Generator)) of the original manifest, if the original manifest was used for the returned shipment; or

B) Item 20 (Designated Facility Owner or Operator. Certification of hazardous materials covered by the manifest except as noted in Item 18a) of the new manifest, if a new manifest was used for the returned shipment;

2) Provide the transporter a copy of the manifest;

3) Within 30 days after receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

4) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of Section 726.608(a).

i) Reporting by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) Biennial Reporting by Healthcare Facilities. Healthcare facilities are not subject to annual reporting requirements under 35 Ill. Adm. Code 722.141, with respect to non-creditable hazardous waste pharmaceuticals managed under this Subpart P.

2) Exception Reporting by Healthcare Facilities for a Missing Copy of the Manifest

A) For Shipments from a Healthcare Facility to a Designated Facility. If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days after the date when the initial transporter accepted the non-creditable hazardous waste pharmaceuticals, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

B) For Shipments Rejected by the Designated Facility and Shipped to an Alternate Facility. If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days after the date when the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility accepted the non-creditable hazardous waste, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

3) Additional Reports. The Agency may, in writing, require a healthcare facility to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

j) Recordkeeping by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) A healthcare facility must keep a copy of each manifest signed in accordance with 35 Ill. Adm. Code 722.123(a) for three years or until it receives a signed copy from the designated facility that received the non-creditable hazardous waste pharmaceuticals. The healthcare facility must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the waste.

2) A healthcare facility must keep a copy of each exception report for a period of at least three years after the date of the report.

3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determinations consistent with 35 Ill. Adm. Code 722.111(f), for at least three years after the date the waste was last sent to onsite or off-site

treatment, storage, or disposal. A healthcare facility that manages all of its non-creditable nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of its hazardous waste determinations.

4) The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested in writing by the Agency.

5) A healthcare facility must make all records readily available upon request by a USEPA or Agency inspector.

k) Response to Spills of Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this Subpart P.

l) Accepting Non-Creditable Hazardous Waste Pharmaceuticals from an Off-Site Healthcare Facility That Is a VSQG. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under 35 Ill. Adm. Code 722.114, without a permit or without having interim status, provided the receiving healthcare facility fulfills the following conditions:

1) The receiving healthcare facility is under the control of the same person (as defined in 35 Ill. Adm. Code 720.110) as the VSQG healthcare facility sending the non-creditable hazardous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility. ("Control", for the purposes of this subsection (l)(1), means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise. A contractor that operates a healthcare facility on behalf of a different person, as defined in 35 Ill. Adm. Code 720.110, does not "control" a healthcare facility);

2) The receiving healthcare facility is operating under this Subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

3) The receiving healthcare facility manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this Subpart P; and

4) The receiving healthcare facility keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years after the date when it received the shipment.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.603 Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

a) Hazardous Waste Determination for Potentially Creditable Pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is a listed hazardous waste in Subpart D of 35 Ill. Adm. Code 721 or exhibits a characteristic of hazardous waste identified in Subpart C of 35 Ill. Adm. Code 721). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this Subpart P.

b) Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from an Off-Site Healthcare Facility That Is a VSQG. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under 35 Ill. Adm. Code 722.114 without a permit or interim status, provided the receiving healthcare facility fulfills the following conditions:

1) The receiving healthcare facility is under the control of the same person (as defined in 35 Ill. Adm. Code 720.110) as the VSQG healthcare facility sending the potentially creditable hazardous waste pharmaceuticals off site, or the sending healthcare facility has a contractual or other documented business relationship in which the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

2) The receiving healthcare facility is operating under this Subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

3) The receiving healthcare facility manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this Subpart P; and

4) The receiving healthcare facility keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

c) Prohibition. A healthcare facility is prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

d) Annual Reporting by Healthcare Facilities. A healthcare facility is not subject to annual reporting requirements under 35 Ill. Adm. Code 722.141 with respect to potentially creditable hazardous waste pharmaceuticals managed under this Subpart P.

e) Recordkeeping by Healthcare Facilities

1) A healthcare facility initiating a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment for three years after the date of shipment:

A) The confirmation of delivery; and

B) The shipping papers prepared in accordance with subpart C of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111, if applicable.

2) The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

3) All records must be readily available upon request by a USEPA or Agency inspector.

f) Response to Spills of Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this Subpart P.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.604 Very Small Quantity Generators

a) Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

b) Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by a Healthcare Facility That Is a VSQG. A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided either of the following is true:

1) The receiving healthcare facility meets the conditions in Sections 726.602(l) and 726.603(b), as applicable; or

2) The VSQG healthcare facility meets the conditions in 35 Ill. Adm. Code 722.114(a)(5)(H) and the receiving LQG meets the conditions in 35 Ill. Adm. Code 722.117(f).

c) Long-Term Care Facilities That Are VSQGs. A long-term care facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, that is registered with the federal Drug Enforcement Administration (DEA) provided the contents are collected, stored, transported, destroyed, and disposed of in compliance with all applicable DEA regulations for controlled substances in 21 CFR 1300 through 1317, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding 40 CFR 266.504(c) allows on-site disposal into a collection receptacle of "an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration". The DEA rules for management of controlled substances are in 21 CFR 1300 through 1317. The DEA registration rules are in 21 CFR 1301.

d) Long-Term Care Facilities with 20 Beds or Fewer. A long-term care facility with 20 beds or fewer is presumed to be a VSQG subject to 35 Ill. Adm. Code 722.114 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this Subpart P, except for Sections 726.605 and 726.607 and the other optional provisions of this Section. The Agency has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of those applicable to a VSQG, as defined in 35 Ill. Adm. Code 720.110. A long-term care facility with more than 20 beds that operates as a VSQG under 35 Ill. Adm. Code 722.114 must demonstrate that it generates quantities of hazardous waste that are within those applicable to a VSQG, as defined by 35 Ill. Adm. Code 720.110.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.605 Prohibition Against Sewering

All healthcare facilities, including VSQGs operating under 35 Ill. Adm. Code 722.114 in lieu of this Subpart P, and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1), incorporated by reference in 35 Ill. Adm. Code 720.111.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.606 Conditional Exemptions for Controlled Substances and Household Hazardous Waste Pharmaceuticals

a) Conditional Exemptions. Provided the conditions of subsection (b) are met, the following are exempt from 35 Ill. Adm. Code 722 through 733:

1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by DEA in 21 CFR 1308.11 through 1308.15, incorporated by reference in 35 Ill. Adm. Code 720.111; and

2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, that is registered with DEA and that commingles the household waste pharmaceuticals with controlled substances from an "ultimate user", as defined in 21 USC 802(27), incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding 40 CFR 266.506(a)(2) exempts from regulation as hazardous waste hazardous waste pharmaceuticals collected in a take-back event or program by "an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration". DEA rules define "collector" in 21 CFR 130001. The DEA registration rules are in 21 CFR 1301.

b) Conditions for Exemption. The following conditions apply to hazardous waste pharmaceuticals:

1) The hazardous waste pharmaceuticals must be managed in compliance with the sewer prohibition of Section 726.605;

2) The hazardous waste pharmaceuticals must be collected, stored, transported, and disposed of in compliance with all applicable DEA regulations for controlled substances in 21 CFR 1300 through 1317, incorporated by reference in 35 Ill. Adm. Code 720.111; and

3) The hazardous waste pharmaceuticals must be rendered "non-retrievable", as defined in 21 CFR 1300.05, under 21 CFR 1317.90 and 1317.95, each incorporated by reference in 35 Ill. Adm. Code 720.111, by a DEA registrant using a method that complies with this DEA standard of destruction or combusted at one of the following facilities:

A) A permitted large municipal waste combustor, subject to the standards of subpart FFF of 40 CFR 62 or applicable state plan for existing large municipal waste combustors, or subpart Eb of 40 CFR 60 for new large municipal waste combustors;

B) A permitted small municipal waste combustor, subject to subpart JJJ of 40 CFR 62 or applicable state plan for existing small municipal waste combustors, or subpart AAAA of 40 CFR 60 for new small municipal waste combustors;

C) A permitted hospital, medical and infectious waste incinerator, subject to subpart HHH of 40 CFR 62 or applicable state plan for existing hospital, medical, and infectious waste incinerators, or subpart Ec of 40 CFR 60 for new hospital, medical, and infectious waste incinerators;

D) A permitted commercial and industrial solid waste incinerator, subject to subpart III of 40 CFR 62 or applicable state plan for existing commercial and industrial solid waste incinerators, or subpart CCCC of 40 CFR 60 for new commercial and industrial solid waste incinerators; or

E) A permitted hazardous waste combustor subject to subpart EEE of 40 CFR 63.

BOARD NOTE: Corresponding 40 CFR 266.506(b)(3) allows destruction by a method deemed in writing by DEA to render the pharmaceutical "non-retrievable". USEPA was not aware of any DEA methods approvals when adopting the rule. USEPA intended that destruction comply with applicable DEA requirements. 84 Fed. Reg. 5816, 5897 (Feb. 22, 2019); 21 CFR 1317.90(a) (2019); 79 Fed. Reg. 53520, 53541 (Sep. 9, 2014). The entity performing the destruction must be a DEA registrant.

Management of controlled substances is authorized within the scope of DEA registration. 21 USC 822(b) (2018).

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.607 Residues in Empty Containers

a) Stock, Dispensing and Unit-Dose Containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, delivery device, etc.) is considered empty and the residues are not regulated as hazardous waste, provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or unit-dose container using the practices commonly employed to remove materials from that type of container.

b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this Subpart P, provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this Subpart P and any applicable federal, State, and local requirements for sharps containers and medical waste.

c) Intravenous (IV) Bags. An IV bag is considered empty and the residues are not regulated as hazardous waste, provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this Subpart P, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty, as defined in 35 Ill. Adm. Code 721.107(b)(1).

d) Other Containers, Including Delivery Devices. Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this Subpart P, unless the container held nonacute hazardous waste pharmaceuticals and is empty, as defined in 35 Ill. Adm. Code 721.107(b)(1) or (b)(2). This includes residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.608 Shipping from a Healthcare Facility or Reverse Distributor

a) Shipping Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following requirements:

1) The following pre-transport requirements, before transporting or offering for transport off-site:

A) Packaging. Applicable USDOT regulations on hazardous materials under 49 CFR 173, 178, and 180, each incorporated by reference in 35 Ill. Adm. Code 720.111;

B) Labeling. Applicable USDOT regulations on hazardous materials under subpart E of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111;

C) Marking

i) Applicable USDOT regulations for hazardous materials under subpart D of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111;

ii) Mark each container of 119 gallons (450 ℓ) or less used in such transportation with the following words and information in accordance with 49 CFR 172.304, incorporated by reference in 35 Ill. Adm. Code 720.111:

HAZARDOUS WASTE – Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____

Healthcare Facility's or Reverse distributor's USEPA Identification Number _____

Manifest Tracking Number _____

iii) Lab packs that will be incinerated in compliance with 35 Ill. Adm. Code 728.142(c) are not required to be marked with USEPA hazardous waste numbers, except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the USEPA hazardous waste numbers; and

D) Placarding. Placard or offer the initial transporter the appropriate placards according to USDOT regulations for hazardous materials under subpart F of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111.

2) The manifest requirements of Subpart B of 35 Ill. Adm. Code 722, except as follows:

A) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of USEPA Form 8700-12.

B) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word "PHARMS" in Item 13 of USEPA Form 8700-12.

b) Exporting Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Subpart H of 35 Ill. Adm. Code 722.

c) Importing Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Subpart H of 35 Ill. Adm. Code 722. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals without a permit or interim status allowing the facility or distributor to accept hazardous waste from off site.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.609 Shipping to a Reverse Distributor

a) Shipping Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that transports or offers for transport potentially creditable hazardous waste pharmaceuticals offsite to a reverse distributor must comply with all applicable USDOT regulations in 49 CFR 171 through 180, incorporated by reference in 35 Ill. Adm. Code 720.111, for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: For purposes of the USDOT regulations, a material is considered a hazardous waste if it is subject to USEPA's hazardous waste manifest requirements in 40 CFR 262 (corresponding with 35 Ill. Adm. Code 722 in Illinois). Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under USDOT regulations.

b) Delivery Confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor initiating the shipment that the shipment has arrived at its destination and is under the custody and control of the reverse distributor.

c) Procedures for When Delivery Confirmation is Not Received within 35 Calendar Days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days after the date when it sent the shipment of potentially creditable hazardous waste pharmaceuticals, the healthcare facility or reverse distributor that initiated the shipment must promptly contact the carrier and the intended recipient (i.e., the reverse distributor) to report that it did not receive the delivery confirmation and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

d) Exporting Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with subsections (a) through (c) and the applicable requirements of Subpart D of 35 Ill. Adm. Code 722, except the manifesting requirement of 35 Ill. Adm. Code 722.183(c).

e) Importing Potentially Creditable Hazardous Waste Pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the

United States is subject to subsections (a) through (c) in lieu of Subpart H of 35 Ill. Adm. Code 722. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this Subpart P.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.610 Standards for Reverse Distributors

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that the reverse distributor complies with the following conditions:

a) Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals

1) Notification. A reverse distributor must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor operating under this Subpart P.

A) A reverse distributor that already has a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, within 60 days after the effective date of this Subpart P, or within 60 days after becoming subject to this Subpart P.

B) A reverse distributor that does not have a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, within 60 days after becoming subject to this Subpart P.

2) Inventory by the Reverse Distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the reverse distributor has accumulated on site.

A) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days after each waste arrived at the reverse distributor.

B) The inventory must include the identity (e.g., name or National Drug Code) and quantity of each potentially creditable hazardous

waste pharmaceutical and evaluated hazardous waste pharmaceutical.

BOARD NOTE: The National Drug Code (NDC) is a three-segment number (including labeler code, product code, and package code) uniquely identifying drugs. The Food and Drug Administration (FDA) assigns the labeler code, and the labeler assigns the product and package codes. 21 CFR 207.33. The NDC is required in applications for registration. 21 CFR 1.74(a) and 1.75(a). The FDA maintains an Internet database for NDC look-up (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory). The FDA requests but does not require use of the NDC on the product label. 21 CFR 201.2. However, when required on drug packaging, the bar code includes the NDC. 21 CFR 201.25(c).

C) If the reverse distributor already meets the inventory requirements of this subsection (a)(2) through compliance with other regulatory requirements, such as under the Pharmacy Practice Act [225 ILCS 85] and 68 Ill. Adm. Code 1330, or the Wholesale Drug Distribution Licensing Act [225 ILCS 120] and 68 Ill. Adm. Code 1510, the facility is not required to provide a separate inventory pursuant to this Section.

3) Evaluation by a Reverse Distributor That Is Not a Manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days after the waste arrived at the reverse distributor to establish whether the waste is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

A) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (b).

B) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (c).

4) Evaluation by a Reverse Distributor That Is a Manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days after the waste arrived at the facility, and the reverse distributor must manage the evaluated hazardous waste pharmaceuticals in accordance with subsection (c) following the evaluation.

5) Maximum Accumulation Time for Hazardous Waste Pharmaceuticals at a Reverse Distributor

A) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 or fewer calendar days. The 180 days start after the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether the pharmaceuticals are destined for another reverse distributor (i.e., the pharmaceuticals are potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., the pharmaceuticals are evaluated hazardous waste pharmaceuticals).

B) Aging Pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the reverse distributor manages the unexpired pharmaceuticals in accordance with subsection (a) and the container labeling and management standards in subsection (c)(4).

6) Security at the Reverse Distributor Facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where the reverse distributor keeps potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

A) Examples of methods that a reverse distributor may use to prevent unknowing entry and minimize the possibility for unauthorized entry include the following:

i) A 24-hour continuous monitoring surveillance system;

ii) An artificial barrier such as a fence; or

iii) A means to control entry, such as keycard access.

B) If the reverse distributor already meets the security requirements of this subsection (a)(6) through compliance with other regulatory requirements, such as federal DEA or Department of Financial and Professional Regulation rules, the facility is not required to provide separate security measures pursuant to this Section.

7) Contingency Plan and Emergency Procedures at a Reverse Distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of Subpart M of 35 Ill. Adm. Code 722.

8) Closure of a Reverse Distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with 35 Ill. Adm. Code 722.117(a)(8)(B) and (a)(8)(C).

9) Reporting by a Reverse Distributor

A) Unauthorized Waste Report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste, etc.). The reverse distributor must prepare and submit an unauthorized waste report to the Agency within 45 calendar days after the unauthorized waste arrives at the reverse distributor, and the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor or its authorized representative. The report must contain the following information:

i) The USEPA identification number, name, and address of the reverse distributor;

ii) The date the reverse distributor received the unauthorized waste;

iii) The USEPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

iv) A description and the quantity of each unauthorized waste the reverse distributor received;

v) The method of treatment, storage, or disposal for each unauthorized waste; and

vi) A brief explanation of why the waste was unauthorized, if known.

B) Additional Reports. The Agency may require a reverse distributor to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the Agency determines in writing are necessary to demonstrate compliance with this Subpart P.

10) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) A copy of its notification under Section 726.602 on file for as long as the facility is subject to this Subpart P;

B) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years after the date when the shipment arrives at the reverse distributor;

C) A copy of its current inventory for as long as the facility is subject to this Subpart P.

b) Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in subsection (a), for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section 726.609.

4) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years after the date of shipment. The retention periods referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) The confirmation of delivery; and

B) The USDOT shipping papers prepared in accordance with subpart C of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111, if applicable.

c) Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals. A reverse distributor that does not have a permit or

interim status must comply with the following conditions, in addition to the requirements of subsection (a), for the management of evaluated hazardous waste pharmaceuticals:

1) Accumulation Area at the Reverse Distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

2) Inspections of On-Site Accumulation Area. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

3) Personnel Training at a Reverse Distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 35 Ill. Adm. Code 722.117(a)(7).

4) Labeling and Management of Containers at On-Site Accumulation Areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must do the following:

A) Label the containers with the words "hazardous waste pharmaceuticals";

B) Ensure the containers are in good condition and managed to prevent leaks;

C) Use containers that are made of, or lined with, materials that will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

D) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, and sealed packaging or in repackaged, intact, and sealed packaging, they meet the closed-container standard;

E) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that

the container does not have the potential to do any of the following:

i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

v) Through other like means threaten human health or the environment; and

F) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

5) Hazardous Waste Numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the USEPA hazardous waste numbers.

6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage, or disposal facility in accordance with the applicable shipping standards in Section 726.608(a) or (b).

7) Procedures for a Reverse Distributor for Managing Rejected Shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the returned evaluated hazardous waste pharmaceuticals on

site for up to an additional 90 days in the on-site accumulation area, provided the rejected or returned shipment is managed in accordance with subsections (a) and (c). Upon receipt of the returned shipment, the reverse distributor must do the following:

A) Sign the appropriate of the following:

i) Item 18c (Signature of Alternate Facility (or Generator)) of the original manifest, if the original manifest was used for the returned shipment; or

ii) Item 20 (Designated Facility Owner or Operator. Certification of hazardous materials covered by the manifest except as noted in Item 18a) of the new manifest, if a new manifest was used for the returned shipment;

B) Provide the transporter a copy of the manifest;

C) Within 30 days after receipt of the rejected shipment of evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

D) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Section 726.608(a) or (b).

8) Land Disposal Restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 35 Ill. Adm. Code 728.107(a) requirements.

9) Reporting by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) Biennial Reporting by a Reverse Distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of an annual report to the Agency by March 1 of each year in accordance with 35 Ill. Adm. Code 722.141.

B) Exception Reporting by a Reverse Distributor for a Missing Copy of the Manifest

i) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 35 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals, the reverse distributor must contact the transporter or the owner or operator of the designated or alternate facility, as applicable, to determine the status of the evaluated hazardous waste pharmaceuticals. For a shipment from the designated facility to an alternate facility, the 35-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them.

ii) A reverse distributor must submit an exception report to the Agency if it has not received a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 45 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals. In the case of a shipment from the designated facility to an alternate facility, the 45-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

BOARD NOTE: The Board combined 40 CFR 266.510(c)(9)(ii)(A)(1) and (c)(9)(ii)(B)(1) as subsection (c)(9)(B)(i) and 40 CFR 266.510(c)(9)(ii)(A)(2), (c)(9)(ii)(A)(2)(i), (c)(9)(ii)(A)(2)(ii), (c)(9)(ii)(B)(2), (c)(9)(ii)(B)(2)(i), and (c)(9)(ii)(B)(2)(ii) as subsection (c)(9)(B)(ii) to comport with codification requirements.

10) Recordkeeping by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) A reverse distributor must keep a log (written or electronic) of the inspections of its onsite accumulation area required by subsection (c)(2). The reverse distributor must retain this log as a record for at least three years after the date of the inspection.

B) A reverse distributor must keep a copy of each manifest signed in accordance with 35 Ill. Adm. Code 722.123(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. The reverse distributor must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the evaluated hazardous waste pharmaceutical.

C) A reverse distributor must keep a copy of each biennial report for at least three years after the due date of the report.

D) A reverse distributor must keep a copy of each exception report for at least three years after submitting the report.

E) A reverse distributor must keep records to document personnel training, in accordance with 35 Ill. Adm. Code 722.117(a)(7)(A)(iv).

F) All records must be readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this subsection (c)(10) are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

d) When a Reverse Distributor Must Have a Permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 35 Ill. Adm. Code 724, 725, and 727 and the permit requirements of 35 Ill. Adm. Code 703, if the reverse distributor does any of the following:

1) The reverse distributor fails to meet the conditions of this Section;

2) The reverse distributor accepts manifested hazardous waste from off site; or

3) The reverse distributor treats or disposes of hazardous waste pharmaceuticals on site.

2447 (Source: Added at 44 Ill. Reg. _____, effective _____)

AGENCY P vs JCAR 707

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE G: WASTE DISPOSAL
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER c: HAZARDOUS WASTE OPERATING REQUIREMENTS

PART 726
STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTE AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

SUBPART A: GENERAL

Section
726.102 Electronic Reporting

SUBPART C: RECYCLABLE MATERIALS USED IN A MANNER CONSTITUTING DISPOSAL

Section
726.120 Applicability
726.121 Standards Applicable to Generators and Transporters of Materials Used in a Manner that Constitutes Disposal
726.122 Standards Applicable to Storers, Who Are Not the Ultimate Users, of Materials that Are To Be Used in a manner that Constitutes Disposal
726.123 Standards Applicable to Users of Materials that Are Used in a Manner that Constitutes Disposal

SUBPART D: HAZARDOUS WASTE BURNED FOR ENERGY RECOVERY

Section
726.130 Applicability (Repealed)
726.131 Prohibitions (Repealed)
726.132 Standards applicable to generators of hazardous waste fuel (Repealed)
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726.134 Standards applicable to marketers of hazardous waste fuel (Repealed)
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726.140 Applicability (Repealed)
726.141 Prohibitions (Repealed)
726.142 Standards applicable to generators of used oil burned for energy recovery (Repealed)
726.143 Standards applicable to marketers of used oil burned for energy recovery (Repealed)

SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS

726.APPENDIX B Tier I Feed Rate Screening Limits for Total Chlorine
726.APPENDIX C Tier II Emission Rate Screening Limits for Free Chlorine and Hydrogen Chloride
726.APPENDIX D Reference Air Concentrations
726.APPENDIX E Risk-Specific Doses
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726.APPENDIX H Potential PICs for Determination of Exclusion of Waste-Derived Residues
726.APPENDIX I Methods Manual for Compliance with BIF Regulations
726.APPENDIX J Guideline on Air Quality Models (Repealed)
726.APPENDIX K Lead-Bearing Materials that May be Processed in Exempt Lead Smelters
726.APPENDIX L Nickel or Chromium-Bearing Materials that May Be Processed in Exempt Nickel-Chromium Recovery Furnaces
726.APPENDIX M Mercury-Bearing Wastes that May Be Processed in Exempt Mercury Recovery Units
726.TABLE A Exempt Quantities for Small Quantity Burner Exemption

AUTHORITY: Implementing Sections 7.2 and 22.4 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/7.2, 22.4 and 27].

SOURCE: Adopted in R85-22 at 10 Ill. Reg. 1162, effective January 2, 1986; amended in R86-1 at 10 Ill. Reg. 14156, effective August 12, 1986; amended in R87-26 at 12 Ill. Reg. 2900, effective January 15, 1988; amended in R89-1 at 13 Ill. Reg. 18606, effective November 13, 1989; amended in R90-2 at 14 Ill. Reg. 14533, effective August 22, 1990; amended in R90-11 at 15 Ill. Reg. 9727, effective June 17, 1991; amended in R91-13 at 16 Ill. Reg. 9858, effective June 9, 1992; amended in R92-10 at 17 Ill. Reg. 5865, effective March 26, 1993; amended in R93-4 at 17 Ill. Reg. 20904, effective November 22, 1993; amended in R94-7 at 18 Ill. Reg. 12500, effective July 29, 1994; amended in R95-4/R95-6 at 19 Ill. Reg. 10006, effective June 27, 1995; amended in R95-20 at 20 Ill. Reg. 11263, effective August 1, 1996; amended in R96-10/R97-3/R97-5 at 22 Ill. Reg. 754, effective December 16, 1997; amended in R97-21/R98-3/R98-5 at 22 Ill. Reg. 18042, effective September 28, 1998; amended in R99-15 at 23 Ill. Reg. 9482, effective July 26, 1999; amended in R00-13 at 24 Ill. Reg. 9853, effective June 20, 2000; amended in R02-1/R02-12/R02-17 at 26 Ill. Reg. 6667, effective April 22, 2002; amended in R03-7 at 27 Ill. Reg. 4200, effective February 14, 2003; amended in R03-18 at 27 Ill. Reg. 12916, effective July 17, 2003; amended in R06-5/R06-6/R06-7 at 30 Ill. Reg. 3700, effective February 23, 2006; amended in R06-16/R06-17/R06-18 at 31 Ill. Reg. 1096, effective December 20, 2006; amended in R07-5/R07-14 at 32 Ill. Reg. 12741, effective July 14, 2008; amended in R11-2/R11-16 at 35 Ill. Reg. 18117, effective October 14, 2011; amended in R13-5 at 37 Ill. Reg. 3249, effective March 4, 2013; amended in R13-15 at 37 Ill. Reg. 17888, effective October 24, 2013; amended in R16-7 at 40 Ill. Reg. 11955, effective August 9, 2016; amended in R17-14/R17-15/R18-12/R18-31 at 42

Ill. Reg. 23023, effective November 19, 2018; amended in R20-3/R20-11 at 44 Ill. Reg. ____, effective _____.

SUBPART G: SPENT LEAD-ACID BATTERIES BEING RECLAIMED

Section 726.180 Applicability and Requirements

a) Extent of Exemption for Spent Lead-Acid Batteries from Hazardous Waste Management Requirements. If an owner or operator generates, collects, transports, stores, or regenerates lead-acid batteries for reclamation purposes, the owner or operator may be exempt from certain hazardous waste management requirements. Subsections (a)(1) though (a)(5) indicate which requirements apply to the owner or operator. Alternatively, the owner or operator may choose to manage its spent lead-acid batteries under the "Universal Waste" rule in 35 Ill. Adm. Code 733.

1) If the spent lead-acid batteries will be reclaimed through regeneration (such as by electrolyte replacement), the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, 722 through 726 (except for 35 Ill. Adm. Code 722.111), and 728 and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111.

2) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator generates, collects, or transports the batteries, the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

3) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator stores the batteries, but the owner or operator is not the reclaimer, the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), but the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

4) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator stores the batteries before the owner or operator reclaims them, the owner or operator must comply with the requirements of Section 726.180(b) and other requirements described in that subsection, and the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

5) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the owner or operator does not store the batteries before the owner or operator reclaims them, the owner or operator is exempt from the requirements of 35 Ill. Adm. Code 702, 703, and 722 through 726 (except for 35 Ill. Adm. Code 722.111), and the notification requirements of section 3010 of RCRA (42 USC 6930), and the owner or operator is subject to the requirements of 35 Ill. Adm. Code 721 and 722.111 and applicable provisions of 35 Ill. Adm. Code 728.

6) If the spent lead-acid batteries will be reclaimed through regeneration or any other means, and the batteries are exported for reclamation in a foreign country, the owner or operator is exempt from 35 Ill. Adm. Code 702, 703, 722 (except for 35 Ill. Adm. Code 722.111, 722.112 and Subpart H of 35 Ill. Adm. Code 722), 723 through 726, and 728, and the notification requirements at section 3010 of RCRA (42 USC 6930). The owner or operator is subject to the requirements of 35 Ill. Adm. Code 721, 722.111, and 722.112 and Subpart H of 35 Ill. Adm. Code 722.

7) If the spent lead-acid batteries will be reclaimed through regeneration or any other means, the person that transports the batteries in the United States to export them for reclamation in a foreign country (the transporter) is exempt from 35 Ill. Adm. Code 702, 703, 723 through 726, and 728, and the notification requirements at section 3010 of RCRA (42 USC 6930). The transporter must comply with the applicable requirements in Subpart H of 35 Ill. Adm. Code 722.

8) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country and stores them but is not the reclaimer, the person is exempt from 35 Ill. Adm. Code 722 (except for 35 Ill. Adm. Code 722.111 and 722.112 and Subpart H of 35 Ill. Adm. Code 722), 702, 703, 723, 724, 725, and 726, and the notification requirements at section 3010 of RCRA (42 USC 6930). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

9) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country and stores them before reclaiming them, the person must comply with 35 Ill. Adm. Code 726.180(b) and as appropriate other regulatory provisions described in 35 Ill. Adm. Code 726.180(b). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

10) If the spent lead-acid batteries will be reclaimed other than through regeneration, and the person that imports the batteries from a foreign country does not store them before reclaiming ~~reclaiming~~ them, the person is exempt from 35 Ill. Adm. Code 702, 703, 722 (except for 35 Ill. Adm. Code 722.111 and 722.112 and Subpart H of 35 Ill. Adm. Code 722), 723, 724, 725, and 726 and the notification requirements at

section 3010 of RCRA (42 USC 6930). The person is subject to 35 Ill. Adm. Code 721, 722.111, 722.112, Subpart H of 35 Ill. Adm. Code 722, and applicable provisions of 35 Ill. Adm. Code 728.

b) Exemption for Spent Lead-Acid Batteries Stored before Reclamation Other Than Through Regeneration. The requirements of this subsection (b) apply to an owner or operator that stores spent lead-acid batteries before it reclaims them, where the owner or operator does not reclaim them through regeneration. The requirements are slightly different depending on the owner's or operator's RCRA permit status.

1) For an interim status facility, the owner or operator must comply with the following requirements:

A) The notification requirements under Section 3010 of RCRA (42 USC 6930);

B) All applicable provisions in Subpart A of 35 Ill. Adm. Code 725;

C) All applicable provisions in Subpart B of 35 Ill. Adm. Code 725, except 35 Ill. Adm. Code 725.113 (waste analysis);

D) All applicable provisions in Subparts C and D of 35 Ill. Adm. Code 725;

E) All applicable provisions in Subpart E of 35 Ill. Adm. Code 725, except 35 Ill. Adm. Code 725.171 and 725.172 (dealing with the use of the manifest and manifest discrepancies);

F) All applicable provisions in Subparts F through L of 35 Ill. Adm. Code 725;

G) All applicable provisions in 35 Ill. Adm. Code 702 and 703; and

H) All applicable provisions in 35 Ill. Adm. Code 727.

2) For a permitted facility, the following requirements:

A) The notification requirements under section 3010 of RCRA (42 USC 6930);

B) All applicable provisions in Subpart A of 35 Ill. Adm. Code 724;

C) All applicable provisions in Subpart B of 35 Ill. Adm. Code 724, except 35 Ill. Adm. Code 724.113 (waste analysis);

D) All applicable provisions in Subparts C and D of 35 Ill. Adm. Code 724;

E) All applicable provisions in Subpart E of 35 Ill. Adm. Code 724, except 35 Ill. Adm. Code 724.171 or 724.172 (dealing with the use of the manifest and manifest discrepancies);

F) All applicable provisions in Subparts F through L of 35 Ill. Adm. Code 724;

G) All applicable provisions in 35 Ill. Adm. Code 702 and 703; and

H) All applicable provisions in 35 Ill. Adm. Code 727.

(Source: Amended at 44 Ill. Reg. _____, effective _____)

SUBPART H: HAZARDOUS WASTE BURNED IN BOILERS AND INDUSTRIAL FURNACES

Section 726.202 Permit Standards for Burners

a) Applicability

1) General. An owner or operator of a BIF that burns hazardous waste and which does not operate under interim status must comply with the requirements of this Section and 35 Ill. Adm. Code 703.208 and 703.232, unless exempt pursuant to the small quantity burner exemption of Section 726.208.

2) Applicability of 35 Ill. Adm. Code 724 Standards. An owner or operator of a BIF that burns hazardous waste is subject to the following provisions of 35 Ill. Adm. Code 724, except as provided otherwise by this Subpart H:

A) In Subpart A (General), 35 Ill. Adm. Code 724.104;

B) In Subpart B (General facility standards), 35 Ill. Adm. Code 724.111 through 724.118;

C) In Subpart C (Preparedness and prevention), 35 Ill. Adm. Code 724.131 through 724.137;

D) In Subpart D (Contingency plan and emergency procedures), 35 Ill. Adm. Code 724.151 through 724.156;

E) In Subpart E (Manifest system, recordkeeping and reporting), the applicable provisions of 35 Ill. Adm. Code 724.171 through 724.177;

F) In Subpart F (Releases from Solid Waste Management Units), 35 Ill. Adm. Code 724.190 and 724.201;

G) In Subpart G (Closure and post-closure), 35 Ill. Adm. Code 724.211 through 724.215;

H) In Subpart H (Financial requirements), 35 Ill. Adm. Code 724.241, 724.242, 724.243, and 724.247 through 724.251, except that the State of

Illinois and the federal government are exempt from the requirements of Subpart H of 35 Ill. Adm. Code 724; and

I) Subpart BB (Air emission standards for equipment leaks), except 35 Ill. Adm. Code 724.950(a).

b) Hazardous Waste Analysis

1) The owner or operator must provide an analysis of the hazardous waste that quantifies the concentration of any constituent identified in Appendix H of 35 Ill. Adm. Code 721 that is reasonably expected to be in the waste. Such constituents must be identified and quantified if present, at levels detectable by using appropriate analytical methods. The constituents listed in Appendix H of 35 Ill. Adm. Code 721 that are excluded from this analysis must be identified and the basis for their exclusion explained. This analysis must provide all information required by this Subpart H and 35 Ill. Adm. Code 703.208 and 703.232 and must enable the Agency to prescribe such permit conditions as are necessary to adequately protect human health and the environment. Such analysis must be included as a portion of the Part B permit application, or, for facilities operating under the interim status standards of this Subpart H, as a portion of the trial burn plan that may be submitted before the Part B application pursuant to provisions of 35 Ill. Adm. Code 703.232(g), as well as any other analysis required by the Agency. The owner or operator of a BIF not operating under the interim status standards must provide the information required by 35 Ill. Adm. Code 703.208 and 703.232 in the Part B application to the greatest extent possible.

2) Throughout normal operation, the owner or operator must conduct sampling and analysis as necessary to ensure that the hazardous waste, other fuels, and industrial furnace feedstocks fired into the BIF are within the physical and chemical composition limits specified in the permit.

c) Emissions Standards. An owner or operator must comply with emissions standards provided by Sections 726.204 through 726.207.

d) Permits

1) The owner or operator must burn only hazardous wastes specified in the facility permit and only under the operating conditions specified pursuant to subsection (e), except in approved trial burns under the conditions specified in 35 Ill. Adm. Code 703.232.

2) Hazardous wastes not specified in the permit must not be burned until operating conditions have been specified under a new permit or permit modification, as applicable. Operating requirements for new wastes must be based on either trial burn results or alternative data included with Part B of a permit application pursuant to 35 Ill. Adm. Code 703.208.

3) BIFs operating under the interim status standards of Section 726.203 are permitted pursuant to procedures provided by 35 Ill. Adm. Code 703.232(g).

4) A permit for a new BIF (those BIFs not operating under the interim status standards) must establish appropriate conditions for each of the applicable requirements of this Section, including but not limited to allowable hazardous waste firing rates and operating conditions necessary to meet the requirements of subsection (e), in order to comply with the following standards:

A) For the period beginning with initial introduction of hazardous waste and ending with initiation of the trial burn, and only for the minimum time required to bring the device to a point of operational readiness to conduct a trial burn, not to exceed a duration of 720 hours operating time when burning hazardous waste, the operating requirements must be those most likely to ensure compliance with the emission standards of Sections 726.204 through 726.207, based on the Agency's engineering judgment. If the applicant is seeking a waiver from a trial burn to demonstrate conformance with a particular emission standard, the operating requirements during this initial period of operation must include those specified by the applicable provisions of Section 726.204, Section 726.205, Section 726.206, or Section 726.207. The Agency must extend the duration of this period for up to 720 additional hours when good cause for the extension is demonstrated by the applicant.

B) For the duration of the trial burn, the operating requirements must be sufficient to demonstrate compliance with the emissions standards of Sections 726.204 through 726.207 and must be in accordance with the approved trial burn plan;

C) For the period immediately following completion of the trial burn, and only for the minimum period sufficient to allow sample analysis, data computation, submission of the trial burn results by the applicant, review of the trial burn results, and modification of the facility permit by the Agency to reflect the trial burn results, the operating requirements must be those most likely to ensure compliance with the emission standards Sections 726.204 through 726.207 based on the Agency's engineering judgment.

D) For the remaining duration of the permit, the operating requirements must be those demonstrated in a trial burn or by alternative data specified in 35 Ill. Adm. Code 703.208, as sufficient to ensure compliance with the emissions standards of Sections 726.204 through 726.207.

e) Operating Requirements

1) General. A BIF burning hazardous waste must be operated in accordance with the operating requirements specified in the permit at all times when there is hazardous waste in the unit.

2) Requirements to Ensure Compliance with the Organic Emissions Standards

A) DRE (destruction or removal efficiency) Standard. Operating conditions must be specified in either of the following ways: on a case-by-case basis for each hazardous waste burned, which conditions must be demonstrated (in a trial burn or by alternative data, as specified in 35 Ill. Adm. Code 703.208) to be sufficient to comply with the DRE performance standard of Section 726.204(a), or as special operating requirements provided by Section 726.204(a)(4) for the waiver of the DRE trial burn. When the DRE trial burn is not waived pursuant to Section 726.204(a)(4), each set of operating requirements must specify the composition of the hazardous waste (including acceptable variations in the physical and chemical properties of the hazardous waste that will not affect compliance with the DRE performance standard) to which the operating requirements apply. For each such hazardous waste, the permit must specify acceptable operating limits including, but not limited to, the following conditions, as appropriate:

i) Feed rate of hazardous waste and other fuels measured and specified as prescribed in subsection (e)(6);

ii) Minimum and maximum device production rate when producing normal product expressed in appropriate units, measured and specified as prescribed in subsection (e)(6);

iii) Appropriate controls of the hazardous waste firing system;

iv) Allowable variation in BIF system design or operating procedures;

v) Minimum combustion gas temperature measured at a location indicative of combustion chamber temperature, measured, and specified as prescribed in subsection (e)(6);

vi) An appropriate indicator of combustion gas velocity, measured and specified as prescribed in subsection (e)(6), unless documentation is provided pursuant to 35 Ill. Adm. Code 703.232 demonstrating adequate combustion gas residence time; and

vii) Such other operating requirements as are necessary to ensure that the DRE performance standard of Section 726.204(a) is met.

B) CO and Hydrocarbon (HC) Standards. The permit must incorporate a CO limit and, as appropriate, a HC limit as provided by Section 726.204(b), (c), (d), (e), and (f). The permit limits must be specified as follows:

i) When complying with the CO standard of Section 726.204(b)(1), the permit limit is 100 ppmv;

ii) When complying with the alternative CO standard pursuant to Section 726.204(c), the permit limit for CO is based on the trial burn

and is established as the average over all valid runs of the highest hourly rolling average CO level of each run; and, the permit limit for HC is 20 ppmv (as defined in Section 726.204(c)(1)), except as provided in Section 726.204(f); or

iii) When complying with the alternative HC limit for industrial furnaces pursuant to Section 726.204(f), the permit limit for HC and CO is the baseline level when hazardous waste is not burned as specified by that subsection.

C) Start-Up and Shut-Down. During start-up and shut-down of the BIF, hazardous waste (except waste fed solely as an ingredient under the Tier I (or adjusted Tier I) feed rate screening limits for metals and chloride/chlorine, and except low risk waste exempt from the trial burn requirements pursuant to Sections 726.204(a)(5), 726.205, 726.206, and 726.207) must not be fed into the device, unless the device is operating within the conditions of operation specified in the permit.

3) Requirements to Ensure Conformance with the Particulate Matter (PM) Standard

A) Except as provided in subsections (e)(3)(B) and (e)(3)(C), the permit must specify the following operating requirements to ensure conformance with the PM standard specified in Section 726.205:

i) Total ash feed rate to the device from hazardous waste, other fuels, and industrial furnace feedstocks, measured and specified as prescribed in subsection (e)(6);

ii) Maximum device production rate when producing normal product expressed in appropriate units, and measured and specified as prescribed in subsection (e)(6);

iii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any air pollution control system (APCS);

iv) Allowable variation in BIF system design including any APCS or operating procedures; and

v) Such other operating requirements as are necessary to ensure that the PM standard in Section 726.205(a) is met.

B) Permit conditions to ensure conformance with the PM standard must not be provided for facilities exempt from the PM standard pursuant to Section 726.205(b);

C) For cement kilns and light-weight aggregate kilns, permit conditions to ensure compliance with the PM standard must not limit the ash content of hazardous waste or other feed materials.

4) Requirements to Ensure Conformance with the Metals Emissions Standard

A) For conformance with the Tier I (or adjusted Tier I) metals feed rate screening limits of Section 726.206(b) or (e), the permit must specify the following operating requirements:

i) Total feed rate of each metal in hazardous waste, other fuels and industrial furnace feedstocks measured and specified pursuant to provisions of subsection (e)(6);

ii) Total feed rate of hazardous waste measured and specified as prescribed in subsection (e)(6); and

iii) A sampling and metals analysis program for the hazardous waste, other fuels and industrial furnace feedstocks;

B) For conformance with the Tier II metals emission rate screening limits pursuant to Section 726.206(c) and the Tier III metals controls pursuant to Section 726.206(d), the permit must specify the following operating requirements:

i) Maximum emission rate for each metal specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste and pumpable hazardous waste, each measured and specified as prescribed in subsection (e)(6)(A);

iii) Feed rate of each metal in the following feedstreams, measured and specified as prescribed in subsections (e)(6): total feed streams; total hazardous waste feed; and total pumpable hazardous waste feed;

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(4)(ii)(C)(1) and (e)(4)(ii)(C)(2) into this subsection (e)(4)(B)(iii) to comport with Illinois Administrative Code codification requirements.

iv) Total feed rate of chlorine and chloride in total feed streams measured and specified as prescribed in subsection (e)(6);

v) Maximum combustion gas temperature measured at a location indicative of combustion chamber temperature, and measured and specified as prescribed in subsection (e)(6);

vi) Maximum flue gas temperature at the inlet to the PM APCS measured and specified as prescribed in subsection (e)(6);

vii) Maximum device production rate when producing normal product expressed in appropriate units and measured and specified as prescribed in subsection (e)(6);

viii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

ix) Allowable variation in BIF system design including any APCS or operating procedures; and

x) Such other operating requirements as are necessary to ensure that the metals standards pursuant to Section 726.206(c) or (d) are met.

C) For conformance with an alternative implementation approach approved by the Agency pursuant to Section 726.206(f), the permit must specify the following operating requirements:

i) Maximum emission rate for each metal specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste and pumpable hazardous waste, each measured and specified as prescribed in subsection (e)(6)(A);

iii) Feed rate of each metal in the following feedstreams, measured and specified as prescribed in subsection (e)(6): total hazardous waste feed; and total pumpable hazardous waste feed;

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(4)(iii)(C)(1) and (e)(4)(iii)(C)(2) into this subsection (e)(4)(C)(iii) to comport with Illinois Administrative Code codification requirements.

iv) Total feed rate of chlorine and chloride in total feed streams measured and specified prescribed in subsection (e)(6);

v) Maximum combustion gas temperature measured at a location indicative of combustion chamber temperature, and measured and specified as prescribed in subsection (e)(6);

vi) Maximum flue gas temperature at the inlet to the PM APCS measured and specified as prescribed in subsection (e)(6);

vii) Maximum device production rate when producing normal product expressed in appropriate units and measured and specified as prescribed in subsection (e)(6);

viii) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

ix) Allowable variation in BIF system design including any APCS or operating procedures; and

x) Such other operating requirements as are necessary to ensure that the metals standards pursuant to Section 726.206(c) or (d) are met.

5) Requirements to Ensure Conformance with the HCl and Chlorine Gas Standards

A) For conformance with the Tier I total chlorine and chloride feed rate screening limits of Section 726.207(b)(1), the permit must specify the following operating requirements:

i) Feed rate of total chlorine and chloride in hazardous waste, other fuels and industrial furnace feedstocks measured and specified as prescribed in subsection (e)(6);

ii) Feed rate of total hazardous waste measured and specified as prescribed in subsection (e)(6); and

iii) A sampling and analysis program for total chlorine and chloride for the hazardous waste, other fuels and industrial furnace feedstocks;

B) For conformance with the Tier II HCl and chlorine gas emission rate screening limits pursuant to Section 726.207(b)(2) and the Tier III HCl and chlorine gas controls pursuant to Section 726.207(c), the permit must specify the following operating requirements:

i) Maximum emission rate for HCl and for chlorine gas specified as the average emission rate during the trial burn;

ii) Feed rate of total hazardous waste measured and specified as prescribed in subsection (e)(6);

iii) Total feed rate of chlorine and chloride in total feed streams, measured and specified as prescribed in subsection (e)(6);

iv) Maximum device production rate when producing normal product expressed in appropriate units, measured and specified as prescribed in subsection (e)(6);

v) Appropriate controls on operation and maintenance of the hazardous waste firing system and any APCS;

vi) Allowable variation in BIF system design including any APCS or operating procedures; and

vii) Such other operating requirements as are necessary to ensure that the HCl and chlorine gas standards pursuant to Section 726.207(b)(2) or (c) are met.

6) Measuring Parameters and Establishing Limits Based on Trial Burn Data

A) General Requirements. As specified in subsections (e)(2) through (e)(5), each operating parameter must be measured, and permit limits on the parameter must be established, according to either of the following procedures:

i) Instantaneous Limits. A parameter is measured and recorded on an instantaneous basis (i.e., the value that occurs at any time) and the

permit limit specified as the time-weighted average during all valid runs of the trial burn; or

ii) Hourly Rolling Average. The limit for a parameter must be established and continuously monitored on an hourly rolling average basis, as defined in Section 726.200(i). The permit limit for the parameter must be established based on trial burn data as the average over all valid test runs of the highest hourly rolling average value for each run.

BOARD NOTE: The Board has combined the text of 40 CFR 266.102(e)(6)(i)(B)(1) and (e)(6)(i)(B)(2) into this subsection (e)(6)(A)(ii) and moved the text of 40 CFR 266.102(e)(6)(i)(B)(1)(i) and (e)(6)(i)(B)(1)(ii) to appear as definitions of "continuous monitor" and "hourly rolling average", respectively, in Section 726.200(i) to comport with Illinois Administrative Code codification requirements.

B) Rolling Average Limits for Carcinogenic Metals and Lead. Feed rate limits for the carcinogenic metals (as defined in Section 726.200(i)) and lead must be established either on an hourly rolling average basis, as prescribed by subsection (e)(6)(A), or on (up to) a 24 hour rolling average basis. If the owner or operator elects to use an average period from 2 to 24 hours, the following requirements apply:

i) The feed rate of each metal must be limited at any time to ten times the feed rate that would be allowed on an hourly rolling average basis;

ii) The continuous monitor must meet the specifications of "continuous monitor", "rolling average for the selected averaging period", and "one hour block average" as defined in Section 726.200(i); and

BOARD NOTE: The Board has moved the text of 40 CFR 266.102(e)(6)(ii)(B)(1) and (e)(6)(ii)(B)(2) to appear as definitions in Section 726.200(i) to comport with Illinois Administrative Code codification requirements.

iii) The permit limit for the feed rate of each metal must be established based on trial burn data as the average over all valid test runs of the highest hourly rolling average feed rate for each run.

C) Feed Rate Limits for Metals, Total Chlorine and Chloride, and Ash. Feed rate limits for metals, total chlorine and chloride, and ash are established and monitored by knowing the concentration of the substance (i.e., metals, chloride/chlorine and ash) in each feedstream and the flow rate of the feedstream. To monitor the feed rate of these substances, the flow rate of each feedstream must be monitored pursuant to the continuous monitoring requirements of subsections (e)(6)(A) and (e)(6)(B).

D) Conducting ~~Conduct of~~ Trial Burn Testing~~.~~

i) If compliance with all applicable emissions standards of Sections 726.204 through 726.207 is not demonstrated simultaneously during a set of test runs, the operating conditions of additional test runs required to demonstrate compliance with remaining emissions standards must be as close as possible to the original operating conditions.

ii) Prior to obtaining test data for purposes of demonstrating compliance with the emissions standards of Sections 726.204 through 726.207 or establishing limits on operating parameters pursuant to this Section, the unit must operate under trial burn conditions for a sufficient period to reach steady-state operations. However, industrial furnaces that recycle collected PM back into the furnace and that comply with an alternative implementation approach for metals pursuant to Section 726.206(f) need not reach steady state conditions with respect to the flow of metals in the system prior to beginning compliance testing for metals emissions.

iii) Trial burn data on the level of an operating parameter for which a limit must be established in the permit must be obtained during emissions sampling for the pollutants (i.e., metals, PM, HCl/chlorine gas, organic compounds) for which the parameter must be established as specified by this subsection (e).

7) General Requirements

A) Fugitive Emissions. Fugitive emissions must be controlled in one of the following ways:

i) By keeping the combustion zone totally sealed against fugitive emissions;

ii) By maintaining the combustion zone pressure lower than atmospheric pressure; or

iii) By an alternative means of control demonstrated (with Part B of the permit application) to provide fugitive emissions control equivalent to maintenance of combustion zone pressure lower than atmospheric pressure.

B) Automatic Waste Feed Cutoff. A BIF must be operated with a functioning system that automatically cuts off the hazardous waste feed when operating conditions deviate from those established pursuant to this Section. In addition, the following requirements apply:

i) The permit limit for (the indicator of) minimum combustion chamber temperature must be maintained while hazardous waste or hazardous waste residues remain in the combustion chamber;

ii) Exhaust gases must be ducted to the APCS operated in accordance with the permit requirements while hazardous waste or hazardous waste residues remain in the combustion chamber; and

iii) Operating parameters for which permit limits are established must continue to be monitored during the cutoff, and the hazardous waste feed must not be restarted until the levels of those parameters comply with the permit limits. For parameters that are monitored on an instantaneous basis, the Agency must establish a minimum period of time after a waste feed cutoff during which the parameter must not exceed the permit limit before the hazardous waste feed is restarted.

C) Changes. A BIF must cease burning hazardous waste when combustion properties or feed rates of the hazardous waste, other fuels or industrial furnace feedstocks, or the BIF design or operating conditions deviate from the limits as specified in the permit.

8) Monitoring and Inspections

A) The owner or operator must monitor and record the following, at a minimum, while burning hazardous waste:

i) If specified by the permit, feed rates and composition of hazardous waste, other fuels, and industrial furnace feedstocks and feed rates of ash, metals, and total chlorine and chloride;

ii) If specified by the permit, CO, HCs, and oxygen on a continuous basis at a common point in the BIF downstream of the combustion zone and prior to release of stack gases to the atmosphere in accordance with operating requirements specified in subsection (e)(2)(B). CO, HC, and oxygen monitors must be installed, operated, and maintained in accordance with methods specified in Appendix I; and

iii) Upon the request of the Agency, sampling and analysis of the hazardous waste (and other fuels and industrial furnace feedstocks as appropriate), residues, and exhaust emissions must be conducted to verify that the operating requirements established in the permit achieve the applicable standards of Sections 726.204, 726.205, 726.206, and 726.207.

B) All monitors must record data in units corresponding to the permit limit unless otherwise specified in the permit.

C) The BIF and associated equipment (pumps, valves, pipes, fuel storage tanks, etc.) must be subjected to thorough visual inspection when it contains hazardous waste, at least daily for leaks, spills, fugitive emissions, and signs of tampering.

D) The automatic hazardous waste feed cutoff system and associated alarms must be tested at least once every seven days when hazardous waste is burned to verify operability, unless the applicant demonstrates to the Agency that weekly inspections will unduly restrict or upset operations and that less frequent inspections will be adequate. At a minimum, operational testing must be conducted at least once every 30 days.

E) These monitoring and inspection data must be recorded and the records must be placed in the operating record required by 35 Ill. Adm. Code 724.173.

9) Direct Transfer to the Burner. If hazardous waste is directly transferred from a transport vehicle to a BIF without the use of a storage unit, the owner and operator must comply with Section 726.211.

10) Recordkeeping. The owner or operator must maintain in the operating record of the facility all information and data required by this Section for five years.

11) Closure. At closure, the owner or operator must remove all hazardous waste and hazardous waste residues (including, but not limited to, ash, scrubber waters, and scrubber sludges) from the BIF.

(Source: Amended at 44 Ill. Reg. ____, effective _____)

SUBPART M: MILITARY MUNITIONS

Section 726.305 Standards Applicable to the Storage of Solid Waste Military Munitions

a) Criteria for Hazardous Waste Regulation of Waste Non-Chemical Military Munitions in Storage

1) Waste military munitions in storage that exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721 are listed or identified as a hazardous waste (and thus are subject to regulation pursuant to 35 Ill. Adm. Code 702, 703, 705, 720 through 728, 733, 738, and 739), unless all the following conditions are met:

A) The waste military munitions are not chemical agents or chemical munitions;

B) The waste military munitions must be subject to the jurisdiction of the Department of Defense Explosives Safety Board (DDESB);

C) The waste military munitions must be stored in accordance with the DDESB storage standards applicable to waste military munitions;

D) Within 90 days of when a storage unit is first used to store waste military munitions, the owner or operator must notify the Agency of the location of any waste storage unit used to store waste military munitions for which the conditional exemption in subsection (a)(1) is claimed;

E) The owner or operator must provide oral notice to the Agency within 24 hours from the time the owner or operator becomes aware of any loss or theft of the waste military munitions, or any failure to meet a

condition of subsection (a)(1) that may endanger health or the environment. In addition, a written submission describing the circumstances must be provided within five days from the time the owner or operator becomes aware of any loss or theft of the waste military munitions or any failure to meet a condition of subsection (a)(1);

F) The owner or operator must inventory the waste military munitions at least annually, must inspect the waste military munitions at least quarterly for compliance with the conditions of subsection (a)(1), and must maintain records of the findings of these inventories and inspections for at least three years; and

G) Access to the stored waste military munitions must be limited to appropriately trained and authorized personnel.

2) The conditional exemption in subsection (a)(1) from regulation as hazardous waste must apply only to the storage of non-chemical waste military munitions. It does not affect the regulatory status of waste military munitions as hazardous wastes with regard to transportation, treatment or disposal.

3) The conditional exemption in subsection (a)(1) applies only so long as all of the conditions in subsection (a)(1) are met.

b) Notice of Termination of Waste Storage. The owner or operator must notify the Agency when a storage unit identified in subsection (a)(1)(D) will no longer be used to store waste military munitions.

c) Reinstatement of Conditional Exemption

1) If any waste military munition loses its conditional exemption pursuant to subsection (a)(1), an application may be filed with the Agency for reinstatement of the conditional exemption from hazardous waste storage regulation with respect to such munition as soon as the munition is returned to compliance with the conditions of subsection (a)(1).

2) If the Agency finds that reinstatement of the conditional exemption is appropriate, it must reinstate the conditional exemption of subsection (a)(1) in writing. The Agency's decision to reinstate or not to reinstate the conditional exemption must be based on two considerations ~~considertions~~: first, the nature of the risks to human health and the environment posed by the waste; and second, either the owner's or operator's provision of a satisfactory explanation of the circumstances of the violation or any demonstration that the violations are not likely to recur. If the Agency denies an application, it must transmit to the applicant specific, detailed statements in writing as to the reasons it denied the application. In reinstating the conditional exemption pursuant to subsection (a)(1), the Agency may specify additional conditions as are necessary to ensure and document proper storage to adequately protect human health and the environment.

3) The Agency may terminate a conditional exemption reinstated by default pursuant to subsection (c)(2) in writing if it finds that reinstatement is inappropriate based on its consideration of the factors set forth in subsection (c)(2). If the Agency terminates a reinstated exemption, it must transmit to the applicant specific, detailed statements in writing as to the reasons it terminated the reinstated exemption.

4) The applicant pursuant to this subsection (c) may appeal the Agency's determination to deny the reinstatement, to grant the reinstatement with conditions, or to terminate a reinstatement before the Board pursuant to Section 40 of the Act.

d) Waste Chemical Munitions

1) Waste military munitions are subject to the applicable regulatory requirements of RCRA subtitle C if the munitions satisfy two conditions: first, they are chemical agents or chemical munitions; and second, they exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721.

2) Waste military munitions are not subject to the storage prohibition in RCRA section 3004(j), codified at 35 Ill. Adm. Code 728.150, if the munitions satisfy two conditions: first, they are chemical agents or chemical munitions; and second, they exhibit a hazardous waste characteristic or are listed as hazardous waste pursuant to 35 Ill. Adm. Code 721.

e) Amendments to DDESB Storage Standards. The DDESB storage standards applicable to waste military munitions, referenced in subsection (a)(1)(C), are DOD 6055.9-STD ("DOD Ammunition and Explosive Safety Standards"), in effect on November 8, 1995, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding federal provision 40 CFR 266.205(e), as added at 62 Fed. Reg. 6656 (Feb. 12, 1997), further provides as follows: "Any amendments to the DDESB storage standards must become effective for purposes of paragraph (a)(1) of this section on the date the Department of Defense publishes notice in the Federal Register that the DDESB standards referenced in paragraph (a)(1) of this section have been amended." Section 5-75 of the Illinois Administrative Procedure Act [5 ILCS 100/5-75] prohibits the incorporation of later amendments and editions by reference. For this reason, interested members of the regulated community will need to notify the Board of any amendments of these references before those amendments can become effective under Illinois law.

(Source: Amended at 44 Ill. Reg. ____, effective _____)

SUBPART P: HAZARDOUS WASTE PHARMACEUTICALS

Section 726.600 Definitions

The following definitions apply to this Subpart P:

"Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with Section 726.610(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of ~~manufacture~~manufacturer credit.

"Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code 721.102, and ~~which~~that exhibits one or more characteristics identified in Subpart C of 35 Ill. Adm. Code 721 or ~~which~~that is listed in Subpart D of 35 Ill. Adm. Code 721. A pharmaceutical is not a solid waste, as defined in 35 Ill. Adm. Code 721.102, and therefore is not a hazardous waste pharmaceutical, if it is legitimately used or reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in 35 Ill. Adm. Code 721.102, and therefore is not a hazardous waste pharmaceutical, if there is a reasonable expectation of its being legitimately used or reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

"Healthcare facility" means any person that is lawfully authorized to do the following:

Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care and counseling, service, assessment, or procedure with respect to the physical or mental condition or functional status of a human or animal or affecting the structure or function of the human or animal body; or

Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical treatment centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

"Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code 721.102, but ~~which~~that is excluded from being a hazardous waste under 35 Ill. Adm. Code 721.104(b)(1).

"Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals, to one or more individuals at the facility. This definition includes hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

"Non-creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used or reused or reclaimed. This includes investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and cleanup material from the spills of pharmaceuticals.

"Non-hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in 35 Ill. Adm. Code ~~721.102, and which~~721.102; is not listed in Subpart D of 35 Ill. Adm. Code ~~721,~~721; and ~~which~~ does not exhibit a characteristic identified in Subpart C of 35 Ill. Adm. Code 721.

"Non-pharmaceutical hazardous waste" means a solid waste, as defined in 35 Ill. Adm. Code 721.102, that is listed in Subpart D of 35 Ill. Adm. Code 721, ~~or which~~ exhibits one or more characteristics identified in Subpart C of 35 Ill. Adm. Code 721, but ~~which~~ is not a pharmaceutical, as defined in this Section.

"Pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes dietary supplements, as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 USC 321(ff)), incorporated by reference in 35 Ill. Adm. Code 720.111; prescription drugs, as defined in 21 CFR 203.3(y), incorporated by reference in 35 Ill. Adm. Code 720.111; over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in nonempty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

"Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and of which the following is true:

It is in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

It is undispensed; and

It is unexpired or less than one year past its expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals, including over-the-counter drugs, homeopathic drugs, and dietary supplements.

"Reverse distributor" means any person that receives and accumulates prescription pharmaceuticals ~~which~~that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.601 Applicability

a) A healthcare facility that is a VSQG when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 35 Ill. Adm. Code 722.114 and is not subject to this Subpart P, except for Sections 726.605 and 726.607 and the optional provisions of Section 726.604.

b) A healthcare facility that is a VSQG when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with Section 726.601(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with 35 Ill. Adm. Code 722.114 and the optional provisions of Section 726.604.

c) A healthcare facility or reverse distributor remains subject to all applicable requirements in 35 Ill. Adm. Code 722 through 725 with respect to the management of its non-pharmaceutical hazardous waste.

d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to the following in lieu of 35 Ill. Adm. Code 722 through 725:

1) Sections 726.602 and 726.605 through 726.608 with respect to the management of the following:

A) Non-creditable hazardous waste pharmaceuticals~~,~~; and

B) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

2) Sections 726.602(a), 726.603, 726.605 through 726.607, and 726.609 with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and ~~which~~that are destined for a reverse distributor.

e) A reverse distributor is subject to Sections 726.605 through ~~726.610~~726.610, in lieu of 35 Ill. Adm. Code 722 through ~~725~~725, with respect to the management of hazardous waste pharmaceuticals.

f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this Subpart P. Other generators are subject to 35 Ill. Adm. Code 722 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

g) The following are not subject to 35 Ill. Adm. Code 720 through 733, except as otherwise specified:

1) Pharmaceuticals that are not solid waste, as defined by 35 Ill. Adm. Code 721.102, because they are legitimately used or reused (e.g., lawfully donated for their intended purpose) or reclaimed.

2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by 35 Ill. Adm. Code 721.102, because there is a reasonable expectation of their being legitimately used or reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with subpart C of 21 CFR 7. This Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR 1115. This Subpart P applies to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

5) Pharmaceuticals stored according to a preservation order or during an investigation or judicial proceeding, until after the preservation order, investigation, or judicial proceeding has concluded or a decision is made to discard the pharmaceuticals.

6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug

Administration's regulations in 21 CFR 312. This Subpart P applies to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

7) Household waste pharmaceuticals, including those that have been collected by a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, provided the authorized collector complies with the conditional exemption in Section 726.606(a)(2) and (b).

BOARD NOTE: The Drug Enforcement Administration regulations define "collector" in the second segment of the definition of "collection" in 21 CFR 1300.01. The authorized status of the collector is part of the definition.

(Source: Added at 44 Ill. Reg. ____, effective _____)

Section 726.602 Standards for Non-Creditable Hazardous Waste Pharmaceuticals

a) Notification and Withdrawal from this Subpart P for Healthcare Facilities Managing Hazardous Waste Pharmaceuticals

1) Notification. A healthcare facility must notify the Agency, using Notification of RCRA Subtitle C Activities (Site Identification Form) (USEPA Form 8700-12), that it is a healthcare facility operating under this Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using the Site Identification Form) for each site or USEPA identification number.

A) A healthcare facility that already has ~~an~~a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or, if not required to submit an annual report, within 60 days after becoming subject to this Subpart P.

B) A healthcare facility that does not have ~~an~~a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a healthcare facility as part of its next annual report, if it is required to submit one; or if not required to submit an annual report, within 60 days after becoming subject to this Subpart P.

C) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this Subpart P.

BOARD NOTE: Corresponding 40 CFR 266.602(a)(1) requires biennial reporting. The Board has required annual reporting, since Section 20.1

of the Act requires the Agency to assemble annual reports, and only annual facility activity reports will enable the Agency to fulfill this mandate.

2) Withdrawal. A healthcare facility that operated under this Subpart P but is no longer subject to this Subpart P, because it is a VSQG under 35 Ill. Adm. Code 722.114, and ~~which~~that elects to withdraw from this Subpart P, must notify the appropriate ~~Agency~~agency using USEPA Form 8700-12 that it is no longer operating under this Subpart P. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of USEPA Form 8700-12 with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (using USEPA Form 8700-12) for each USEPA identification number.

A) A healthcare facility must submit USEPA Form 8700-12 notifying that it is withdrawing from this Subpart P before it begins operating under the conditional exemption of 35 Ill. Adm. Code 722.114.

B) A healthcare facility must keep a copy of its withdrawal on file for three years after the date of signature on the notification of its withdrawal.

b) Training of Personnel Managing Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must ensure that all personnel managing non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

c) Hazardous Waste Determination for Non-Creditable Pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in Subpart D of 35 Ill. Adm. Code 721 or is listed in Subpart D of 35 Ill. Adm. Code 721) in order to determine whether the waste is subject to this Subpart P. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this Subpart P.

d) Standards for Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and ~~which~~ lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or ~~which~~ mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals,

must manage the container so that it does not have the potential to do any of the following:

A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

D) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

E) Through other like means threaten human health or the environment.

3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to their contents.

4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and nonhazardous non-creditable waste pharmaceuticals in the same container, except that the healthcare facility must accumulate non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) in separate containers and label the containers with all applicable USEPA hazardous waste numbers.

e) Labeling Containers Used to Accumulate Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals".

f) Maximum Accumulation Time for Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the facility has accumulated the non-creditable hazardous waste pharmaceuticals, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

A) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date when the non-creditable hazardous waste pharmaceuticals became a waste;

B) Maintaining an inventory system that identifies the date when the accumulated non-creditable hazardous waste pharmaceuticals first became a waste;

C) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date when any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

g) Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with 35 Ill. Adm. Code 728.107(a) requirements, except that it is not required to identify the USEPA hazardous waste numbers on the land disposal restrictions notification.

h) Procedures for Healthcare Facilities for Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and ~~which~~ later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with subsections (d) and (e). Upon receipt of the returned shipment, the healthcare facility must do the following:

1) Sign the applicable of the following:

A) Item 18c (Signature of Alternate Facility (or Generator)) of the original manifest, if the original manifest was used for the returned shipment; or

B) Item 20 (Designated Facility Owner or Operator. Certification of hazardous materials covered by the manifest except as noted in Item 18a) of the new manifest, if a new manifest was used for the returned shipment;

2) Provide the transporter a copy of the manifest;

3) Within 30 days after receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

4) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of Section 726.608(a).

i) Reporting by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) Biennial Reporting by Healthcare Facilities. Healthcare facilities are not subject to annual reporting requirements under 35 Ill. Adm. Code 722.141, with respect to non-creditable hazardous waste pharmaceuticals managed under this Subpart P.

2) Exception Reporting by Healthcare Facilities for a Missing Copy of the Manifest

A) For Shipments from a Healthcare Facility to a Designated Facility. If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days after the date when the initial transporter accepted the non-creditable hazardous waste pharmaceuticals, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

B) For Shipments Rejected by the Designated Facility and Shipped to an Alternate Facility. If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days after the date when the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility accepted the non-creditable hazardous waste, the healthcare facility must submit the following:

i) A legible copy of the original manifest to the Agency, indicating that the healthcare facility has not received confirmation of delivery; and

ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

3) Additional Reports. The Agency may, in writing, require a healthcare facility to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

j) Recordkeeping by Healthcare Facilities for Non-Creditable Hazardous Waste Pharmaceuticals

1) A healthcare facility must keep a copy of each manifest signed in accordance with 35 Ill. Adm. Code 722.123(a) for three years or until it receives a signed copy from the designated facility that received the non-creditable hazardous waste pharmaceuticals. The healthcare facility must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the waste.

2) A healthcare facility must keep a copy of each exception report for a period of at least three years after the date of the report.

3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determinations consistent with 35 Ill. Adm. Code 722.111(f), for at least three years after the date the waste was last sent to onsite or off-site treatment, storage, or disposal. A healthcare facility that manages all of its non-creditable nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of its hazardous waste determinations.

4) The periods of retention referred to in this ~~section~~Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested in writing by the Agency.

5) A healthcare facility must make all records readily available upon request by a USEPA or Agency inspector.

k) Response to Spills of Non-Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this Subpart P.

l) Accepting Non-Creditable Hazardous Waste Pharmaceuticals from an Off-Site Healthcare Facility That Is a VSQG. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under 35 Ill. Adm. Code 722.114, without a permit or without having interim status, provided the receiving healthcare facility fulfills the following conditions:

1) The receiving healthcare facility is under the control of the same person (as defined in 35 Ill. Adm. Code 720.110) as the VSQG healthcare facility sending the non-creditable hazardous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility. ("Control", for the purposes of this ~~Section~~subsection (l)(1), means the power to direct the policies of the

healthcare facility, whether by the ownership of stock, voting rights, or otherwise. A contractor that operates a healthcare facility on behalf of a different person, as defined in 35 Ill. Adm. Code 720.110, does not "control" a healthcare facility);

2) The receiving healthcare facility is operating under this Subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

3) The receiving healthcare facility manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this Subpart P; and

4) The receiving healthcare facility keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years after the date when it received the shipment.

(Source: Added at 44 Ill. Reg. ____, effective _____)

Section 726.603 Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

a) Hazardous Waste Determination for Potentially Creditable Pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is a listed hazardous waste in ~~subpart~~Subpart D of 35 Ill. Adm. Code 721 or exhibits a characteristic of hazardous waste identified in ~~subpart~~Subpart C of 35 Ill. Adm. Code 721). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this Subpart P.

b) Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from an Off-Site Healthcare Facility That Is a VSQG. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under 35 Ill. Adm. Code ~~722.114,~~722.114 without a permit or interim status, provided the receiving healthcare facility fulfills the following conditions:

1) The receiving healthcare facility is under the control of the same person (as defined in 35 Ill. Adm. Code 720.110) as the VSQG healthcare facility sending the potentially creditable hazardous waste pharmaceuticals off site, or the sending healthcare facility has a contractual or other documented business relationship ~~whereby~~in which the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

2) The receiving healthcare facility is operating under this Subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

3) The receiving healthcare facility manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this Subpart P; and

4) The receiving healthcare facility keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

c) Prohibition. A healthcare facility is prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

d) Annual Reporting by Healthcare Facilities. A healthcare facility is not subject to annual reporting requirements under 35 Ill. Adm. Code 722.141 with respect to potentially creditable hazardous waste pharmaceuticals managed under this Subpart P.

e) Recordkeeping by Healthcare Facilities

1) A healthcare facility initiating a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment for three years after the date of shipment:

A) The confirmation of delivery; and

B) The shipping papers prepared in accordance with subpart C of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111, if applicable.

2) The periods of retention referred to in this ~~section~~Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

3) All records must be readily available upon request by a USEPA or Agency inspector.

f) Response to Spills of Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this Subpart P.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.604 Very Small Quantity Generators

a) Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

b) Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by a Healthcare Facility That Is a VSQG. A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided either of the following is true:

1) The receiving healthcare facility meets the conditions in Sections 726.602(l) and 726.603(b), as applicable; or

2) The VSQG healthcare facility meets the conditions in 35 Ill. Adm. Code 722.114(a)(5)(H) and the receiving LQG meets the conditions in 35 Ill. Adm. Code 722.117(f).

c) Long-Term Care Facilities That Are VSQGs. A long-term care facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, that is registered with the federal Drug Enforcement Administration (DEA) provided the contents are collected, stored, transported, destroyed, and disposed of in compliance with all applicable DEA regulations for controlled substances in 21 CFR 1300 through 1317, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding 40 CFR 266.504(c) allows on-site disposal into a collection receptacle of "an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration". The DEA rules for management of controlled substances are in 21 CFR 1300 through 1317. The DEA registration rules are in 21 CFR 1301.

d) Long-Term Care Facilities with 20 Beds or Fewer. A long-term care facility with 20 beds or fewer is presumed to be a VSQG subject to 35 Ill. Adm. Code 722.114 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this Subpart P, except for Sections 726.605 and 726.607 and the other optional provisions of this Section. The Agency has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of those applicable to a VSQG, as defined in 35 Ill. Adm. Code 720.110. A long-term care facility with more than 20 beds that operates as a VSQG under 35 Ill. Adm. Code 722.114 must demonstrate that it generates

quantities of hazardous waste that are within those applicable to a VSQG, as defined by 35 Ill. Adm. Code 720.110.

(Source: Added at 44 Ill. Reg. ____, effective _____)

Section 726.605 Prohibition ~~against~~Against Sewering

All healthcare facilities~~,~~ including VSQGs operating under 35 Ill. Adm. Code 722.114 in lieu of this Subpart P~~,~~ and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1), incorporated by reference in 35 Ill. Adm. Code 720.111.

(Source: Added at 44 Ill. Reg. ____, effective _____)

Section 726.606 Conditional Exemptions for Controlled Substances and Household Hazardous Waste Pharmaceuticals

a) Conditional Exemptions. Provided the conditions of subsection (b) are met, the following are exempt from 35 Ill. Adm. Code 722 through 733:

1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by ~~the~~ DEA in 21 CFR 1308.11 through 1308.15, incorporated by reference in 35 Ill. Adm. Code 720.111; and

2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by a "collector", as defined in 21 CFR 1300.01, incorporated by reference in 35 Ill. Adm. Code 720.111, that is registered with ~~the federal~~ DEA ~~which~~and that commingles the household waste pharmaceuticals with controlled substances from an "ultimate user", as defined in 21 USC 802(27), incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: Corresponding 40 CFR 266.506(a)(2) exempts from regulation as hazardous waste hazardous waste pharmaceuticals collected in a take-back event or program by "an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration". DEA rules define "collector" in 21 CFR 130001. The DEA registration rules are in 21 CFR 1301.

b) Conditions for Exemption. The following ~~condition~~conditions apply to hazardous waste pharmaceuticals:

1) The hazardous waste pharmaceuticals must be managed in compliance with the sewer prohibition of Section 726.605; ~~and~~

2) The hazardous waste pharmaceuticals must be collected, stored, transported, and disposed of in compliance with all applicable DEA regulations for controlled substances in 21 CFR 1300 through 1317, incorporated by reference in 35 Ill. Adm. Code 720.111; and

3) The hazardous waste pharmaceuticals must be rendered "non-retrievable", as defined in 21 CFR 1300.05, under 21 CFR 1317.90 and 1317.95, each incorporated by reference in 35 Ill. Adm. Code 720.111, by a DEA registrant using a method that complies with this DEA standard of destruction or combusted at one of the following facilities:

A) A permitted large municipal waste combustor, subject to the standards of subpart FFF of 40 CFR 62 or applicable state plan for existing large municipal waste combustors, or subpart Eb of 40 CFR 60 for new large municipal waste combustors; ~~or~~

B) A permitted small municipal waste combustor, subject to subpart JJJ of 40 CFR 62 or applicable state plan for existing small municipal waste combustors, or subpart AAAA of 40 CFR 60 for new small municipal waste combustors; ~~or~~

C) A permitted hospital, medical and infectious waste incinerator, subject to subpart HHH of 40 CFR 62 or applicable state plan for existing hospital, medical, and infectious waste incinerators, or subpart Ec of 40 CFR 60 for new hospital, medical, and infectious waste incinerators~~.~~;

D) A permitted commercial and industrial solid waste incinerator, subject to subpart III of 40 CFR 62 or applicable state plan for existing commercial and industrial solid waste incinerators, or subpart CCCC of 40 CFR 60 for new commercial and industrial solid waste incinerators~~.~~; or

E) A permitted hazardous waste combustor subject to subpart EEE of 40 CFR 63.

BOARD NOTE: Corresponding 40 CFR 266.506(b)(3) allows destruction by a method deemed in writing by DEA to render the pharmaceutical "non-retrievable". USEPA was not aware of any DEA methods approvals when adopting the rule. USEPA intended that destruction comply with applicable DEA requirements. 84 Fed. Reg. 5816, 5897 (Feb. 22, 2019)~~.~~; 21 CFR 1317.90(a) (2019); 79 Fed. Reg. 53520, 53541 (Sep. 9, 2014). The entity performing the destruction must be a DEA registrant. Management of controlled substances is authorized within the scope of DEA registration. 21 USC 822(b) (2018).

(Source: Added at 44 Ill. Reg. _____~~__~~, effective _____~~_____~~)

Section 726.607 Residues in Empty Containers

a) Stock, Dispensing and Unit-Dose Containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, delivery device, etc.) is considered empty and the residues are not regulated as hazardous waste, provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or ~~the~~ unit-dose container using the practices commonly employed to remove materials from that type of container.

b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this Subpart P, provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this Subpart P and any applicable federal, ~~state~~State, and local requirements for sharps containers and medical waste.

c) Intravenous (IV) Bags. An IV bag is considered empty and the residues are not regulated as hazardous waste, provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this Subpart P, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty, as defined in 35 Ill. Adm. Code 721.107(b)(1).

d) Other Containers, Including Delivery Devices. Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this Subpart P, unless the container held nonacute hazardous waste pharmaceuticals and is empty, as defined in 35 Ill. Adm. Code 721.107(b)(1) or (b)(2). This includes residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.608 Shipping from a Healthcare Facility or Reverse Distributor

a) Shipping Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with the following requirements:

1) The following pre-transport requirements, before transporting or offering for transport off-site:

A) Packaging. Applicable USDOT regulations on hazardous materials under 49 CFR 173, 178, and 180, each incorporated by reference in 35 Ill. Adm. Code 720.111;

B) Labeling. Applicable USDOT regulations on hazardous materials under subpart E of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111;

C) Marking

i) Applicable USDOT regulations for hazardous materials under subpart D of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111;

ii) Mark each container of 119 gallons (450 l) or less used in such transportation with the following words and information in accordance with 49 CFR 172.304, incorporated by reference in 35 Ill. Adm. Code 720.111:

HAZARDOUS WASTE - Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address

_____

Healthcare Facility's or Reverse distributor's USEPA Identification Number _____

Manifest Tracking Number _____

iii) Lab packs that will be incinerated in compliance with 35 Ill. Adm. Code 728.142(c) are not required to be marked with USEPA hazardous waste numbers, except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the USEPA hazardous waste numbers; and

D) Placarding. Placard or offer the initial transporter the appropriate placards according to USDOT regulations for hazardous materials under subpart F of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111.

2) The manifest requirements of Subpart B of 35 Ill. Adm. Code 722, except as follows:

A) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of USEPA Form 8700-12.

B) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word "PHARMS" in Item 13 of USEPA Form 8700-12.

b) Exporting Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Subpart H of 35 Ill. Adm. Code 722.

c) Importing Non-Creditable Hazardous Waste Pharmaceuticals or Evaluated Hazardous Waste Pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Subpart H of 35 Ill. Adm. Code 722. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals without a permit or interim status allowing the facility or distributor to accept hazardous waste from off site.

(Source: Added at 44 Ill. Reg. _____, effective _____)

Section 726.609 Shipping to a Reverse Distributor

a) Shipping Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that transports or offers for transport potentially creditable hazardous waste pharmaceuticals offsite to a reverse distributor must comply with all applicable USDOT regulations in 49 CFR 171 through 180, incorporated by reference in 35 Ill. Adm. Code 720.111, for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8, incorporated by reference in 35 Ill. Adm. Code 720.111.

BOARD NOTE: For purposes of the USDOT regulations, a material is considered a hazardous waste if it is subject to USEPA's hazardous waste manifest requirements in 40 CFR 262 (corresponding with 35 Ill. Adm. Code 722 in Illinois). Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under USDOT regulations.

b) Delivery Confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor initiating the shipment that the shipment has arrived at its destination and is under the custody and control of the reverse distributor.

c) Procedures for When Delivery Confirmation is Not Received within 35 Calendar Days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days after the date when it sent the

shipment of potentially creditable hazardous waste pharmaceuticals, the healthcare facility or reverse distributor that initiated the shipment must promptly contact the carrier and the intended recipient (i.e., the reverse distributor) to report that it did not receive the delivery confirmation and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

d) Exporting Potentially Creditable Hazardous Waste Pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with subsections (a) through (c) and the applicable requirements of ~~subpart~~Subpart D of 35 Ill. Adm. Code 722, except the manifesting requirement of 35 Ill. Adm. Code 722.183(c).

e) Importing Potentially Creditable Hazardous Waste Pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to subsections (a) through (c) in lieu of Subpart H of 35 Ill. Adm. Code 722. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this Subpart P.

(Source: Added at 44 Ill. Reg. ___, effective _____)

Section 726.610 Standards for Reverse Distributors

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that the reverse distributor complies with the following conditions:

a) Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals

1) Notification. A reverse distributor must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor operating under this Subpart P.

A) A reverse distributor that already has ~~an~~a USEPA identification number must notify the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, within 60 days ~~of~~after the effective date of this Subpart P, or within 60 days after becoming subject to this Subpart P.

B) A reverse distributor that does not have a USEPA identification number must obtain one by notifying the Agency, using USEPA Form 8700-12, that it is a reverse distributor, as defined in Section 726.600, within 60 days after becoming subject to this Subpart P.

2) Inventory by the Reverse Distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the reverse distributor has accumulated on site.

A) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days after each waste arrived at the reverse distributor.

B) The inventory must include the identity (e.g., name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

BOARD NOTE: The National Drug Code (NDC) is a three-segment number (including labeler code, product code, and package code) uniquely identifying drugs. The Food and Drug Administration (FDA) assigns the labeler code, and the labeler assigns the product and package codes. 21 CFR 207.33. The NDC is required in applications for registration. 21 CFR 1.74(a) and 1.75(a). The FDA maintains an Internet database for NDC look-up (https://www.fda.gov/~~?~~drugs/~~?~~drug-approvals-and-databases/national-drug-code-directory). The FDA requests but does not require use of the NDC on the product label. 21 CFR 201.2. However, ~~where~~when required on drug packaging, the bar code includes the NDC. 21 CFR 201.25(c).

C) If the reverse distributor already meets the inventory requirements of this subsection (a)(2) through compliance with other regulatory requirements, such as under the Pharmacy Practice Act [225 ILCS 85] and 68 Ill. Adm. Code ~~1330~~1330, or the Wholesale Drug Distribution Licensing Act [225 ILCS 120] and 68 Ill. Adm. Code 1510, the facility is not required to provide a separate inventory pursuant to this Section.

3) Evaluation by a Reverse Distributor That Is Not a Manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days after the waste arrived at the reverse distributor to establish whether the waste is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

A) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (b).

B) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical", and the reverse distributor must manage the waste in accordance with subsection (c).

4) Evaluation by a Reverse Distributor That Is a Manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days after the waste arrived at the facility, and the reverse distributor must manage the evaluated hazardous waste pharmaceuticals in accordance with subsection (c) following the evaluation.

5) Maximum Accumulation Time for Hazardous Waste Pharmaceuticals at a Reverse Distributor

A) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 or fewer calendar days ~~or less~~. The 180 days start after the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether the pharmaceuticals are destined for another reverse distributor (i.e., the pharmaceuticals are potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., the pharmaceuticals are evaluated hazardous waste pharmaceuticals).

B) Aging Pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the reverse distributor manages the unexpired pharmaceuticals in accordance with subsection (a) and the container labeling and management standards in ~~Section 726.610~~subsection (c)(4~~)(A) through (c)(4)(F~~).

6) Security at the Reverse Distributor Facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where the reverse distributor keeps potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

A) Examples of methods that a reverse distributor may use to prevent unknowing entry and minimize the possibility for unauthorized entry include the following:

i) A 24-hour continuous monitoring surveillance system;

ii) An artificial barrier such as a fence; or

iii) A means to control entry, such as keycard access.

B) If the reverse distributor already meets the security requirements of this subsection (a)(6) through compliance with other regulatory requirements, such as federal DEA or Department of Financial and

Professional Regulation rules, the facility is not required to provide separate security measures pursuant to this Section.

7) Contingency Plan and Emergency Procedures at a Reverse Distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of Subpart M of 35 Ill. Adm. Code 722.

8) Closure of a Reverse Distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with 35 Ill. Adm. Code 722.117(a)(8)(B) and (a)(8)(C).

9) Reporting by a Reverse Distributor

A) Unauthorized Waste Report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste, etc.). The reverse distributor must prepare and submit an unauthorized waste report to the Agency within 45 calendar days after the unauthorized waste arrives at the reverse distributor, and the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor or its authorized representative. The report must contain the following information:

i) The USEPA identification number, name, and address of the reverse distributor;

ii) The date the reverse distributor received the unauthorized waste;

iii) The USEPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

iv) A description and the quantity of each unauthorized waste the reverse distributor received;

v) The method of treatment, storage, or disposal for each unauthorized waste; and

vi) A brief explanation of why the waste was unauthorized, if known.

B) Additional Reports. The Agency may require a reverse distributor to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that the Agency determines in writing are necessary to demonstrate compliance with this Subpart P.

10) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) A copy of its notification under Section 726.602 on file for as long as the facility is subject to this Subpart P;

B) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years after the date when the shipment arrives at the reverse distributor;

C) A copy of its current inventory for as long as the facility is subject to this Subpart P.

b) Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in subsection (a), for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after evaluating the potentially creditable hazardous waste pharmaceuticals or must follow subsection (c) for evaluated hazardous waste pharmaceuticals.

3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section 726.609.

4) Recordkeeping by Reverse Distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an Agency or USEPA inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another

reverse distributor, for at least three years after the date of shipment. The retention periods referred to in this Section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested in writing by the Agency.

A) The confirmation of delivery; and

B) The USDOT shipping papers prepared in accordance with subpart C of 49 CFR 172, incorporated by reference in 35 Ill. Adm. Code 720.111, if applicable.

c) Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (a), for the management of evaluated hazardous waste pharmaceuticals:

1) Accumulation Area at the Reverse Distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

2) Inspections of On-Site Accumulation Area. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

3) Personnel Training at a Reverse Distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 35 Ill. Adm. Code 722.117(a)(7).

4) Labeling and Management of Containers at On-Site Accumulation Areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must do the following:

A) Label the containers with the words~~,~~ "hazardous waste pharmaceuticals";

B) Ensure the containers are in good condition and managed to prevent leaks;

C) Use containers that are made of, or lined with, materials ~~which~~that will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

D) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, and

sealed packaging or in repackaged, intact, and sealed packaging, they meet the closed-container standard;

E) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to do any of the following:

i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

v) Through other like means threaten human health or the environment; and

F) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 35 Ill. Adm. Code 728.103(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

5) Hazardous Waste Numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the USEPA hazardous waste numbers.

6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage, or disposal facility in accordance with the applicable shipping standards in Section 726.608(a) or (b).

7) Procedures for a Reverse Distributor for Managing Rejected Shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and ~~which~~ later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 35 Ill. Adm. Code 724.172 or 725.172, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area, provided the rejected or returned shipment is managed in accordance with ~~Section 726.610~~subsections (a) and (c). Upon

receipt of the returned shipment, the reverse distributor must do the following:

A) Sign the appropriate of the following:

i) Item 18c (Signature of Alternate Facility (or Generator)) of the original manifest, if the original manifest was used for the returned shipment; or

ii) Item 20 (Designated Facility Owner or Operator. Certification of hazardous materials covered by the manifest except as noted in Item 18a) of the new manifest, if a new manifest was used for the returned shipment;

B) Provide the transporter a copy of the manifest;

C) Within 30 days after receipt of the rejected shipment of evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

D) Within 90 days after receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Section 726.608(a) or (b).

8) Land Disposal Restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 35 Ill. Adm. Code 728. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 35 Ill. Adm. Code 728.107(a) requirements.

9) Reporting by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) Biennial Reporting by a Reverse Distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of an annual report to the Agency by March 1 of each year in accordance with 35 Ill. Adm. Code 722.141.

B) Exception Reporting by a Reverse Distributor for a Missing Copy of the Manifest

i) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 35 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals, the reverse distributor must contact the transporter or the owner or operator of the designated or alternate facility, as applicable, to determine the status of the evaluated hazardous waste pharmaceuticals.

For a shipment from the designated facility to an alternate facility, the 35-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them.

ii) A reverse distributor must submit an exception report to the Agency if it has not received a copy of the manifest with the signature of the owner or operator of the designated or alternate facility within 45 days after the date when the initial transporter accepted the evaluated hazardous waste pharmaceuticals. In the case of a shipment from the designated facility to an alternate facility, the 45-days begin when the transporter forwarding the evaluated hazardous waste pharmaceuticals accepted them. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery~~,~~ and a cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

BOARD NOTE: The Board combined 40 CFR 266.510(c)(9)(ii)(A)(1) and (c)(9)(ii)(B)(1) as subsection (c)(9)(B)(i) and 40 CFR 266.510(c)(9)(ii)(A)(2), (c)(9)(ii)(A)(2)(i), (c)(9)(ii)(A)(2)(ii), (c)(9)(ii)(B)(2), (c)(9)(ii)(B)(2)(i), and (c)(9)(ii)(~~A~~B)(2)(ii) as subsection (c)(9)(B)(ii) to comport with codification requirements.

10) Recordkeeping by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

A) A reverse distributor must keep a log (written or electronic) of the inspections of its onsite accumulation area required by subsection (c)(2). The reverse distributor must retain this log as a record for at least three years after the date of the inspection.

B) A reverse distributor must keep a copy of each manifest signed in accordance with 35 Ill. Adm. Code 722.123(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. The reverse distributor must retain this signed copy as a record for at least three years after the date when the initial transporter accepted the evaluated hazardous waste pharmaceutical.

C) A reverse distributor must keep a copy of each biennial report for at least three years after the due date of the report.

D) A reverse distributor must keep a copy of each exception report for at least three years after submitting the report.

E) A reverse distributor must keep records to document personnel training, in accordance with 35 Ill. Adm. Code 722.117(a)(7)(A)(iv).

F) All records must be readily available upon request by an Agency or USEPA inspector. The periods of retention referred to in this subsection (c)(10) are extended automatically during the course of any

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