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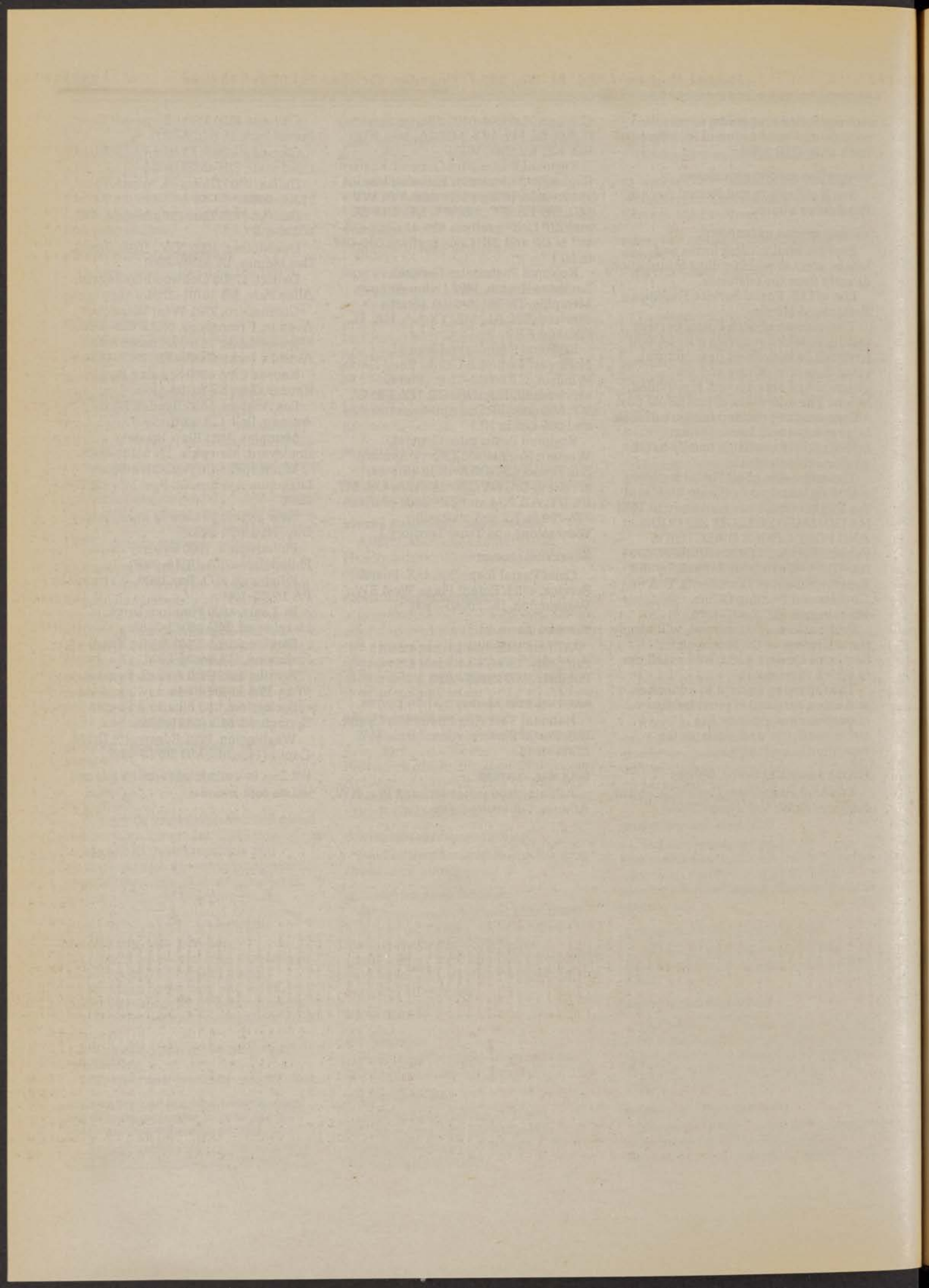San Francisco, 2501 Rydin Road, Richmond, CA 94804-9998.

Seattle, 34301 9th Ave. S. Federal Way, WA 98003-0500.

Springfield, 190 Fiberloid Street, Springfield, MA 01151-1088.

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Thursday
October 26, 1989

Part III

Environmental Protection Agency

40 CFR Part 260 et al.

Burning of Hazardous Waste in Boilers and Industrial Furnaces; Supplement to Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 264, 265, 266, 270, and 271

[FRL-3358-5 EPA/OSW-FR-89-024]

RIN 2050-AA72

Burning of Hazardous Waste in Boilers and Industrial Furnaces

AGENCY: Environmental Protection Agency.

ACTION: Supplement to proposed rule.

SUMMARY: On May 6, 1987 (52 FR 16982), EPA proposed rules to control the burning of hazardous waste in boilers and industrial furnaces. Those rules would control emissions of products of incomplete combustion (PICs), toxic metals, and hydrogen chloride (HC1) as well as require a 99.99% destruction and removal efficiency for hazardous organic constituents in the waste. EPA has received substantial comments on the proposed rules, and as a result, is considering alternative approaches to several provisions of the proposed rule. The Agency is also considering issuance of a proposal to amend the hazardous waste incinerator standards to make those rules consistent with these proposed standards.

The purpose of this notice is to request comment on alternate approaches to address the following issues: control of CO, metals, HC1, and particulate emissions, the small quantity burner exemption, the definition of waste that is indigenous when burned for reclamation (e.g., of metal values), revisions to the proposed definition of halogen acid furnaces, applicability of the metals and organic emissions controls to smelting furnaces involved in materials recovery, and the status under the Bevill amendment of residues from burning hazardous waste.

DATES: EPA will accept public comments on this notice until December 26, 1989. The Agency notes that the comment period is reopened to address only the issues discussed in this notice. The comment period on other issues addressed by the proposed rule closed on July 27, 1987.

ADDRESSES: Comments should be sent to RCRA Docket Section (OS-305), U.S. Environmental Protection Agency, 401 M Street, SW., Washington DC 20460 ATTN: Docket No. F-80-BBSP-FFFFF. The public docket is located in Room 2427 and is available for viewing from 9:00 am to 4:00 pm, Monday thru Friday, excluding legal holidays. Individuals interested in viewing the docket should call (202) 475-9327 for an appointment.

FOR FURTHER INFORMATION CONTACT: RCRA HOTLINE, toll free, at (800) 424-9346 or at (202) 382-3000. Single copies of this notice are available by calling the RCRA Hotline. For technical information, contact Dwight Hlustick, Combustion Section, Waste Management Division, Office of Solid Waste, OS-322, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, Telephone: (202) 382-7917.

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Today's notice is organized into two parts. Part One contains background information that summarizes the major revisions which are being considered to the May 6, 1987, proposed rule. See 52 FR 16982. It also describes how today's

proposed rule would relate to the planned amendments to the incinerator standards that the Agency may soon propose.

Part Two describes the alternative approaches the Agency is considering to address several issues. EPA is requesting comment on these alternatives because they differ substantially from the provisions proposed. The Agency will consider comments on the original proposal as well as on the alternatives discussed here in developing final rules for promulgation. Alternatives on which we are soliciting comment are: adding a particulate standard for boilers and furnaces; and developing alternative standards for carbon monoxide (CO) (to limit products of incomplete combustion (PICs)), toxic metals, and hydrogen chloride (HCl). We also discuss in this part revisions being considered to the small quantity burner exemption to make the risk assessment used to establish the exempt quantities consistent with the assessment used to establish the metals, HCl, and PIC standards. In addition, we discuss in this part an expansion to the definition of waste that would be considered indigenous to particular types of devices when it is reclaimed. Industrial furnaces burning indigenous waste solely for reclamation (i.e., not for energy recovery or destruction) would not be subject to any of the proposed emission standards. Finally, we discuss here the Agency's current thinking on the applicability of the Bevill exclusion (see RCRA section 3001(b)(3)(A) (i)–(iii)) to residues from fossil fuel-fired boilers, cement kilns, and industrial furnaces that process ores and minerals, when such devices also burn or process hazardous waste.

PART ONE: BACKGROUND

I. Legal Authority

These regulations were proposed under the authority of section 1006, 2002(a), 3001, 3004, 3005, and 3007 of the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976, the Quiet Communities Act of 1978, the Solid Waste Disposal Act Amendments of 1980, and the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. 6905, 6912(a), 6921, 6924, 6925, and 6927.

II. Overview of This Notice

The purpose of this notice is to request comments on various alternatives to the May 6, 1987, proposed rule. The alternative approaches the EPA is discussing today may be incorporated in the final rule.

In this notice, EPA is considering a number of changes to the May 6, 1987, proposed rule. Several changes are a result of comments received on the proposal. Others result from the Agency's revised risk assessment approach. As a result, EPA is considering: (1) Adding a particulate emissions standard for boilers and industrial furnaces; (2) alternatives to the proposed carbon monoxide standard based on risks posed by emissions of products of incomplete combustion; (3) establishing emissions controls for six additional toxic metals; (4) revising the small quantity burner exemption to base it on an upgraded risk assessment; and (5) expanding the definition of indigenous waste as it applies to industrial furnaces involved in the reclamation of hazardous wastes.

III. Relationship of This Notice to the May 6, 1987, Proposed Rule

Comments on the alternative approaches discussed in today's notice will be considered as well as comments on the proposed rule in developing a final rule for promulgation. The basic methodology for developing the alternate standards discussed today is the same as used to develop the May 6, 1987, proposal. The conservative Screening Limits discussed today are based on the principle that ground level concentrations of pollutants emitted from a facility must not result in unacceptable health risk to a maximum exposed individual. Thus, these Screening Limits are similar in concept to the Tier I–Tier III metals and HCl Standards proposed in 1987. The major change in the metals and HCl Standards would be to establish limits based on effective stack height (i.e., physical stack height plus plume rise) in lieu of the thermal capacity and type of the combustion device. This would result in less over-regulation because the limits would be established as a function of effective stack height, a key site-specific factor in dispersion of stack emissions.

The risk assessment methodology also remains basically the same as proposed on May 6, 1987. The only change is an upgrading of the air dispersion models based on revisions to EPA-recommended air dispersion models.

Finally, we are updating Appendices A (reference air concentrations) and B (risk specific doses) originally published on May 6, 1987, and corrected on July 8, 1987 to reflect current health effects data. Both Appendices are provided in their entirety as appendices to this notice.

IV. Relationship of This Notice to the Planned Hazardous Waste Incinerator Revisions

It is EPA's intention to make the standards for burning [1] hazardous waste as uniform as possible given that the potential risks posed are similar irrespective of the type of combustion device. This approach also should be easier for both the regulated community and EPA to implement. Accordingly, the Agency is considering a proposal, which may be noticed shortly, to revise the existing hazardous waste incinerator standards under Subpart O of 40 CFR part 264 to provide controls for PICs, metals, and HCl that are identical to those described in today's notice for boilers and industrial furnaces.

The Agency plans to address in a future rulemaking an issue of particular interest to owners and operators of boilers and industrial furnaces; the Agency plans to propose to expand the definition of industrial furnace (which presently applies to only controlled flame devices) to include any of the currently designated devices that are supplied with heat energy by any means. Thus, for example, electric arc smelting furnaces would be included in the definition.

PART TWO: ALTERNATIVES BEING CONSIDERED

I. Particulate Standards

A. Justification for Particulate Standard

EPA received numerous comments on the May 6, 1987, proposed rule suggesting the need for a particulate standard for boilers and furnaces burning hazardous waste. Many respondents believed that unregulated particulate emissions could pose a significant threat to human health because toxic metals and organic compounds may be absorbed onto particulate matter (PM), and because PM, *per se*, could pose a health risk because the smaller size particles may be entrained in the lungs.

[1] For the purpose of this notice, "burning" in industrial furnaces includes reduction as well as combustion. As additional information, EPA plans to propose to expand the definition of industrial furnaces in 40 CFR 260.10 to include those designated furnaces that engage in any form of thermal processing, not just combustion. Thus, that proposal would include as regulated industrial furnaces electric arc smelting furnaces processing metal-bearing hazardous waste to recover metals. The Agency plans to include that proposal in the Federal Register notice to amend the incinerator standards. See discussion in text. The Agency is not including the proposal to expand the definition of industrial furnace in today's notice because this notice is considered a supplemental notice to the May 1987 proposed rule, rather than a new proposed rule or reproposal.

In light of these comments, EPA is considering establishing a particulate emission standard for boilers and industrial furnaces. Even though we believe that the proposed metals and organic emissions standards would adequately protect public health based on current knowledge about toxic pollutants and available risk assessment methodologies, we acknowledge that there are serious limitations to the proposed health-based standards for metals (see section B.3 below). A PM control standard would provide additional protection by ensuring that absorbed metal and organic compounds would be removed from stack gases with the collected PM.

B. Selection of Particulate Standard

EPA is considering limiting particulate emissions from boilers and industrial furnaces based on the current hazardous waste incinerator standard of 0.08 gr/dscf (grains/dry standard cubic foot), corrected to 7 percent oxygen. We are selecting this particulate limit because it would provide a common measure of protection from particulate emissions from boilers, industrial furnaces, and incinerators burning hazardous waste.

We acknowledge that a particulate standard for boilers and industrial furnaces may be redundant in some cases for a number of reasons: (1) EPA may have established (usually more stringent) particulate standards for the facility as New Source Performance Standards (NSPS) under the Clean Air Act; (2) the States may have established particulate standards for the facility under the Clean Air Act's State Implementation Plan (SIP) required to ensure that the National Ambient Air Quality Standard for particulate matter is not exceeded; and (3) the metals and HCl emission standards proposed for boilers and furnaces burning hazardous waste may result in particulate emissions well below 0.08 gr/dscf. We believe, however, that there would be many situations where the standards would not be redundant. As discussed below, NSPS standards would not apply to many boilers and industrial furnaces. SIP standards may not apply to many units with relatively small capacity. Finally, many boilers may burn hazardous waste with low levels of metals and chlorine such that emission controls, if needed, may not lower particulate emissions to 0.08 gr/dscf. Thus, we believe that particulate standard would frequently not be redundant, and where redundant, the additional burden of compliance, if any, would not be significant.

In selecting a particulate standard for boilers and industrial furnaces, we considered the following alternatives:

1. *Apply the current NSPS Standard for Steam Generators Burning Waste.* EPA promulgated NSPS for steam generators burning waste with or without other fuels that limit particulate emissions from new municipal waste combustors (MWCs) to 0.03–0.04 gr/dscf. (See 40 CFR 60.43(b)). New MWCs would be subject to this standard because they almost invariably are designed to recover energy. Thus, the Agency has, in effect, lowered the 0.08 gr/dscf NSPS promulgated in 1981 at 40 CFR 60.52 for new solid waste incinerators to 0.03–0.04 gr/dscf. Given that EPA based the hazardous waste incinerator particulate standard on the 1981 municipal incinerator standard (0.08 gr/dscf), it could be argued that the Agency should lower the hazardous waste incinerator particulate standard accordingly to 0.03–0.04 gr/dscf. This would allow the Agency to take advantage of advances in the state-of-the-art of particulate control technology. However, as explained in Section B.3., EPA is not prepared to propose to lower the hazardous waste incinerator particulate standard at this time. This issue will be discussed further in the planned revisions to the hazardous waste incinerator standards.

2. *Apply the Applicable NSPS.* Under this approach, the particulate matter NSPS applicable to a source category (e.g., cement kilns) would be applied to all units in that category irrespective of date of construction or size. (The NSPS as authorized by the Clean Air Act apply only to new units, and often small-capacity units are exempt.)

EPA has promulgated particulate matter NSPS for a number of devices including boilers; cement kilns; lime kilns; asphalt concrete drying kilns; primary lead, zinc, and copper smelters; and secondary lead and bronze smelters. These standards generally result in particulate emissions concentrations ranging from 0.01 to 0.05 gr/dscf. However, many devices that burn hazardous waste (e.g., light-weight aggregate kilns) are not covered by NSPS regulations. Therefore, standards would have to be developed for these devices. Development of these standards will take a significant amount of time and effort on the part of the Agency.

In addition, the economic impacts of applying the NSPS to existing and small devices may be substantial given that the standards were developed to control particulate emissions to the limit of technical and economic feasibility for

new units (without consideration of retrofitting issues. We discuss below, however, that we are beginning an effort to establish a best demonstrated technology (BDT) particulate standard for boilers and industrial furnaces. In that evaluation, we will consider whether the NSPS represent BDT.

3. *Apply the Existing Hazardous Waste Incinerator Standard.* We believe that the existing hazardous waste incinerator standard of 0.08 gr/dscf (see 40 CFR 340.342(c)) should be applied to all boilers and industrial furnaces burning hazardous waste (unless more stringent NSPS or SIP Standards already apply to the device). This would ensure that the same interim cap on particulate emissions applies to all hazardous waste combustion devices until BDT particulate standards can be developed. The 0.08 gr/dscf standard is readily achievable and should not result in significant economic impacts. Preliminary data indicate that approximately 10–20 percent of boilers and industrial furnaces burning hazardous waste would be required to upgrade or install particulate control equipment or otherwise reduce emissions to meet the standard.

In addition to providing some control of particulate metals and adsorbed organic compounds, the 0.08 gr/dscf standard should also ensure that the National Ambient Air Quality Standard (NAAQS) for particulates is achieved in most cases. An analysis of existing sites shows that emissions of particulates at 0.08 gr/dscf could result in MEI levels of up to 30% of the maximum daily PM_{10} (particulate matter under 10 microns) NAAQS (150 mg/m³). If background particulate levels at a site are already high (i.e., the site is in a non-attainment area), however, particulate emissions from the device should be addressed as part of the State Implementation Plan (SIP) (as they are now for hazardous waste incinerators in particulate non-attainment areas). Therefore, although the 0.08 gr/dscf standard may not ensure compliance with the NAAQS in every situation, this issue will be addressed by the SIP since the facility would be, by definition, in a non-attainment area for particulate emissions.

As mentioned above, EPA is undertaking an effort to investigate a best demonstrated technology (BDT) particulate standard for boilers and industrial furnaces burning hazardous waste. (We are also investigating a BDT particulate standard for hazardous waste incinerators.) Although we believe the proposed metals and PIC controls provide substantial protection

of public health, those risk-based controls have limitations including: (1) Health effects via indirect exposure to carcinogens (e.g., deposition of metals and uptake through the food chain), ecological effects, and synergistic effects have not been considered; (2) without adequate health effects data to establish acceptable ambient levels, emissions limits cannot be established (e.g., we are not proposing emission limits for selenium for this reason); and (3) constituent-specific, risk-based emission limits must be implemented by limiting feed rates, which can be difficult given the variability of waste matrices and pollutant concentrations. Given these concerns, we believe that a BDT particulate standard is necessary to adequately protect public health and the environment. Once the BDT particulate standard is promulgated (after proposal and opportunity for public comment), the risk-based controls would be used to supplement the BDT standard on a case-by-case basis to address situations where the BDT standard may not be fully protective. We specifically request comment on whether NSPS particulate limits can be considered BDT. Further, given that time and budget constraints are likely to limit development of BDT standards for only the primary types of devices that burn hazardous waste (e.g., oil, gas, and coal-fired boilers, cement kilns, light-weight aggregate kilns), we request comment on how BDT particulate standards can be established on a case-by-case basis during the permitting process for other types of devices.

C. Implementation of the Particulate Standard

1. *Preferred Option.* EPA wants facilities in interim status to comply with the particulate standard as quickly as possible and believes that it is reasonable to require compliance within 24 months of promulgation of the final rule. Accordingly, the source would have to demonstrate initial compliance under 40 CFR part 60, appendix A, Methods 1–5, within twelve months of promulgation. The compliance test must be representative of worst-case waste-fuel/operating conditions with respect to particulate emissions that will occur during interim status. Previous testing under the Clean Air Act could be used to make this demonstration if the operating conditions meet the conditions specified above. Final compliance for those sources that are unable to demonstrate initial compliance would be required within 24 months of promulgation (whether or not the facility has received a final RCRA permit). The compliance alternatives are: (1) Modify

operations of the facility to bring it into compliance (e.g., upgrade air pollution control equipment); or (2) implementation of closure (under 40 CFR 265.111). The Regional Administrator could, however, extend the compliance period if the owner or operator can show inability to make the required modifications due to situations beyond its control, e.g., the required equipment is unavailable from vendors within the regulatory time frame. This option is EPA's preferred alternative for implementation of particulate standards.

2. *Alternative Options.* EPA is also considering the following alternative interim status requirements to bring sources into compliance with the particulate standard. One alternative would require facilities that cannot demonstrate compliance (within 12 months of promulgation) to submit a compliance plan to the Agency within 15 months of promulgation which ensures expedient compliance (i.e., within 12 months of Agency approval). Another alternative would require the source to submit a complete Part B, RCRA Permit Application, or to cease burning hazardous waste and complete closure requirements within 18 months of promulgation. EPA requests comments on each of these alternatives to implement the particulate standard as quickly as possible.

II. Alternative PIC Controls

The 1987 proposed boiler and industrial furnace rule would limit flue gas carbon monoxide (CO) levels to ensure that these devices do not emit products of incomplete combustion (PICs) at levels that could pose unacceptable health risk. The Agency discusses here its revised thinking on how best to establish controls on PIC emissions and we are also considering a proposal, which may be noticed shortly, to apply the revised approach to control PIC emissions from hazardous waste incinerators as well. We discuss below the comments received on the proposed rule and describe the revised approach.

A. Comments on Proposed CO Standard

The proposed boiler and industrial furnace rule would have applied the same CO emissions limits to all boilers and industrial furnaces: a lower limit of 100 ppmv over a 60-minute rolling average and a 500 ppmv limit over a 10-minute rolling average. The hazardous waste feed would be automatically cut off if either limit was exceeded, and hazardous waste burning operations would have to cease pending review by enforcement officials if the waste feed were cut off more than 10 times a month. The lower limit of 100 ppmv was

selected as representative of steady-state high efficiency combustion conditions resulting in PIC emissions that would not pose a significant risk. The higher limit of 500 ppmv was proposed to limit the frequency of emission spikes that inevitably accompany routine operational transients, such as load changes and start-up of waste firing.

Many commenters opposed the proposed CO trigger limits and associated limits on the number of waste feed cutoffs. Principally, commenters objected to one set of CO emission limits applicable to all boilers and industrial furnaces. Further, they argued that PIC emissions would not be significant if, when the waste feed was cut off, combustion chamber temperatures were maintained while the waste remained in the chamber. Thus, they argued that there was no need to limit the number of waste feed cutoffs.

Commenters indicated that several types of boilers and many cement kilns would not be able to meet the proposed 100 ppmv limit even though hydrocarbon concentrations would not be high at the elevated CO levels. For example, boilers burning residual oil or coal typically operate with CO emission levels above the proposed 100 ppmv limit because of inherent fuel combustion characteristics, equipment design constraints, routine transient combustion-related events, requirements for multiple fuel flexibility, and compliance with NO_2 emission standards. Attempts to reduce CO emissions from these devices to meet the proposed limits may prove unsuccessful in addition to the possibility of heavy penalties in thermal efficiency if successful.

Similarly, industry and trade groups for the cement industry voiced strong opposition to the 100 ppmv limit for cement kilns. These commenters indicated that some cement kilns, especially modern precalciners, routinely emit CO above the proposed 100 ppmv limit. In general, commenters indicated that while the proposed limits may be appropriate for combustion devices in which only fuel (fossil or hazardous waste) enters the combustion chamber, they are inappropriate for cement kilns and other product kilns in which massive amounts of feedstocks are processed. These feedstocks can generate large quantities of CO emissions which are, in large part, unrelated to the combustion efficiency of burning the waste and fuel. Whereas all the CO from boilers and some industrial furnaces is combustion-generated, the bulk of the CO from product kilns can be the result of

process events unrelated to the combustion conditions at the burner where wastes are introduced.[2] Therefore, limiting CO emissions from these combustion devices to the proposed 100 ppmv level may be difficult and not warranted as a means of minimizing risk from PICs.

In summary, commenters argued that the proposed CO limits would be difficult or virtually impossible to meet in some cases, and, thus, inappropriate given that EPA has not established a direct correlation between CO, PIC emissions, and health risk.

In light of these concerns, commenters suggested that EPA establish CO limits for specific categories of devices based on CO levels achieved by units operating under best operating practices (BOP). We considered this approach but determined that equipment-specific CO trigger limits would be difficult to establish and support and would not necessarily provide adequate protection from PIC emissions. For example, the BOP CO level for a precalcining cement kiln may be 800 ppmv, a level that industry representatives indicate may be typical in some situations for that device. If that CO level, in fact, results in part from the inefficient combustion of hazardous waste, PICs may be emitted at levels that pose significant risk. (We note, however, that PIC emissions may or may not be high when CO levels are high. However, in all known instances, PIC emissions are low when CO levels are under 100 ppmv.)

EPA nonetheless believes that the CO limits should be flexible to avoid major economic impacts on the regulated community given that we cannot say that when CO levels exceed 100 ppmv that PIC emissions will always, or even often, result in significant health risk. At some elevated CO level, however, PIC emissions would pose significant risk. Unfortunately, we cannot at this time identify the precise trigger level—the trigger level may vary by type and design of device and fuel mix. Consequently, we have developed a two-tiered approach to control PICs. Under Tier I, CO would be limited to the 100 ppmv limit proposed in 1987. (See appendix A for background information

on the basis for the Agency's concern about PIC emissions and the use of CO to minimize the potential health risk.) Under Tier II, the 100 ppmv CO limit would be waived under two alternative approaches: (1) a demonstration that total hydrocarbon (THC) emissions are not likely to pose unacceptable health risk using conservative, prescribed risk assessment procedures; or (2) a demonstration that the THC concentration in the stack gas does not exceed a good operating practice-based limit of 20 ppmv. Although we prefer the technology-based approach for reasons discussed below, we request comment on the health-based alternative as well.

B. Proposed Tier II Controls

If the highest hourly average CO level during the trial burn exceeds the Tier I limit of 100 ppmv, a higher CO level would be allowed under two alternative approaches: a health-based approach, or a technology-based approach.[3] We prefer the technology-based approach for reasons discussed below. One of the alternatives will be selected for the final rule based on public comment and Agency evaluation, including a critique by the Agency's Science Advisory Board (SAB).[4]

1. *Health-Based Approach.* Under the health-based approach to waive the 100 ppmv CO limit, the applicant would be allowed to demonstrate that PIC emissions from the combustion device pose an acceptable risk (i.e., less than 10^{-5}) to the maximum exposed individual (MEI). Under this approach, we would require the applicant to quantify total hydrocarbon (THC) emissions during the trial burn and to assume that all hydrocarbons are carcinogenic compounds with a unit risk that has been calculated based on available data. The THC unit risk value would be $1.0 \times 10^{-5} \, m^3/\mu g$ and represents the adjusted, 95th percentile weighted (i.e., by emission concentration) average unit risk of all the hydrocarbon emissions data in our data base of field testing of boilers, industrial furnaces, and incinerators burning hazardous waste. The weighted unit risk value for THC considers

emissions data for carcinogenic PICs (e.g., chlorinated dioxins and furans, benzene, chloroform, carbon tetrachloride) as well as data for PICs that are not suspected carcinogens and are considered to be relatively nontoxic (e.g., methane, and other C_1 as well as C_2 pure hydrocarbons, i.e., containing only carbon and hydrogen). We adjusted the data base as follows to increase the conservatism of the calculated THC unit risk value: (1) We assumed that the carcinogen formaldehyde is emitted from hazardous waste combustion devices at the 95th percentile levels found to be emitted from municipal waste combustors;[5] and (2) we assumed that every carcinogenic compound in Appendix VIII of Part 261 for which we have health effects data but no emissions data is actually emitted at the level of detection of the test methods, 0.1 ng/1. Finally, we assigned a unit risk of zero to noncarcinogenic compounds (e.g., C_1–C_2 hydrocarbons such as methane, acetylene). The calculated unit risk value for THC is $1 \times 10^{-5} \, m^3/\mu g$, comparable to the value for carbon tetrachloride.[6]

To implement the health-based approach with minimum burden on permit writers and applicants, we have established conservative THC emission Screening Limits as a function of effective stack height, terrain, and land use. See appendix B. These Screening Limits were back-calculated from the acceptable ambient level for THC, 1.0 $\mu g/m^3$ (based on the unit risk value discussed above and an acceptable MEI risk of 10^{-5}), using conservative dispersion coefficients. (We also used those dispersion coefficients to develop alternative emissions and feed rate limits for metals and HC1, as discussed below. The basis for those dispersion coefficients is also discussed below.) If THC emissions measured during the trial burn do not exceed the THC emissions Screening Limits, the risk posed by THC emissions would be considered acceptable. If the Screening Limits are exceeded, the applicant would be required to conduct site-specific dispersion modeling using EPA's "Guidelines on Air Quality Models (Revised)" to demonstrate that the

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[2] For example, CO can be generated from the trace levels of organic matter contained in the raw materials as the materials move down the kiln from the cold end to the hot end where the fuel and waste is fired. CO can also be generated by combustion of fossil fuel at the base of the precalciner, which takes combustion gases from the kiln and heats them further with fossil fuel to precalcine the raw materials before feeding into the kiln. Although hazardous waste may not be fired in a precalciner, inefficient combustion of the precalciner fuel will result in high flue gas CO levels.

[3] This two-tiered approach would supersede the approach proposed in 1987 whereby the waste feed would be cutoff within 10 minutes of exceeding a 100 ppmv hourly rolling average CO level and immediately when exceeding a 500 ppmv rolling 10 minute average. We believe that the approach proposed in today's notice is more environmentally conservative and supportable in light of commenters' concerns about the technical support for the dual range CO limits and averaging periods proposed in 1987.

[4] EPA's SAB reviewed the proposed PIC controls in the spring of 1989 and a final report is scheduled to be available in the fall of 1989.

[5] Because of its extremely high violatility, special stack sampling and analysis procedures are required to measure formaldehyde emissions. Such testing has not been successfully conducted during EPA's field testing of hazardous waste combustion devices.

[6] For additional technical support, see U.S. EPA, "Background Information Document for the Development of Regulations for PIC Emissions from Hazardous Waste Incinerators," December, 1988 (Draft Final Report).

(potential) MEI exposure level (i.e., the maximum annual average ground level concentration) does not exceed the acceptable THC ambient level.

2. *Technology-Based Approach.* Under this Tier II approach, the Tier I CO limit of 100 ppmv would be waived if THC levels in the stack gas do not exceed a good operating practice-based limit of 20 ppmv.

We have developed this technology-based approach because of concern about scientific limitations of the risk-based approach. In addition, the risk-based approach could allow THC levels of several hundred ppmv—levels that are clearly indicative of upset combustion conditions.

The Agency believes that risk assessment can and should be used to limit the application of technology-based controls—that is, to demonstrate that additional technology controls, even though available, may not be needed. However, we are sufficiently concerned that our proposed THC risk assessment methodology may have limitations particularly when applied to THC emitted during poor combustion conditions (i.e., situations where CO exceeds 100 ppmv) that we are considering a cap on THC emissions. Although we believe the development of a risk-based approach is a step in the right direction, we are concerned whether the risk-based approach is adequately protective given our limited data base on PIC emissions and understanding of what fraction of organic emissions would be detected by the THC monitoring system. Notwithstanding the limitations of the THC risk assessment methodology, however, we believe it is reasonable to use the methodology to predict whether a technology-based limit appears to be protective. We have used the risk assessment methodology to show that a 20 ppmv THC limit appears to be protective of public health.

We discuss below our concerns with the proposed THC risk-based approach and the basis for tentatively selecting 20 ppmv as the recommended THC limit (measured with a conditioned gas monitoring system, recorded on an hourly rolling average basis, reported as propane, and corrected to 7% oxygen).

a. *Concerns with the THC Risk Assessment Methodology.* Our primary concern with the risk assessment methodology is that, although it may be a reasonable approach for evaluating PIC emissions under good combustion conditions, it may not be adequate for poor combustion conditions—when CO exceeds 100 ppmv. The vast majority of our data on the types and concentrations of PIC emissions from

incinerators, boilers, and industrial furnaces burning hazardous waste were obtained during test burns when the devices were operated under good combustion conditions. CO levels were often well below 50 ppmv. Under Tier II applications, CO levels can be 500 to 10,000 ppmv or higher (there is no upper limit on CO).[7] The concern is that we do not know whether the types and concentrations of PICs at these elevated CO levels, indicative of combustion upset conditions, are similar to the types and concentrations of PICs in our data base. It could be hypothesized that as combustion conditions deteriorate, the ratio of semi- and nonvolatile compounds to volatile compounds may increase. If so, this could have serious impacts on the proposed risk assessment methodology. First, the proposed generic unit risk value for THC may be understated when applied to THC emitted under poor combustion conditions. This is because semi- and nonvolatile compounds comprise only 1% of the mass of THC in our data base, but pose 80% of the estimated cancer risk. Thus, if the fraction of semi- and nonvolatile compounds increases under poor combustion conditions, the cancer risk posed by the compounds may also increase.

To put this concern in perspective, we note that the proposed THC risk value calculated from available data is 1×10^{-5} $m^3/\mu g$. This unit risk is 100 times greater (i.e., more potent) than the unit risk for the quantified PICs with the lowest unit risk (e.g., tetrachloroethylene), but 1000 times lower than the unit risk for PICs such as dibenzoanthracene, and 10,000 to 1,000,000 times lower than the unit risk for various chlorinated dioxins and furans.

Second, if the fraction of semi- and nonvolatile THC increases under poor combustion conditions, the fraction of THC in the vapor phase when entering the THC detector may be lower than the 75% assumed when operating under good combustion conditions.[8] If so, the correction factor for the so-called missing mass would be greater than the 1.33 factor proposed.

The Agency is currently conducting emissions testing to improve the data base in support of the proposed risk-based approach. We are concerned, however, that the testing that is

underway and planned may not provide information adequate to fully address all the issues. In addition, we are concerned that our stack sampling and analysis procedures and our health effects data base are not adequate to satisfactorily characterize the health effects posed by Pics emitted under poor combustion conditions.

A final concern with the risk assessment methodology is that it does not consider health impacts resulting from indirect exposure. As explained above, the risk-based standards proposed today consider human health impacts only from direct inhalation. Indirect exposure via uptake through the food chain, for example, has not been considered because the Agency has not yet developed procedures for quantifying indirect exposure impacts for purposes of establishing regulatory emission limits.

b. *Basis for the THC Limit.* We request comment on a THC limit of 20 ppmv as representative of a THC level distinguishing between good and poor combustion conditions. Under this alternative approach, THC would be monitored continuously during the trial burn, recorded on an hourly average basis, reported as ppmv propane, and corrected to 7% oxygen. (See discussion below in section C.4 regarding performance specifications of the THC monitoring system.) We have tentatively selected a level of 20 ppmv because: (1) It is within the range of values reported in our data base for hazardous waste incinerators and boilers and industrial furnaces burning hazardous waste; and (2) the level appears to be protective of human health based on risk assessments using the proposed methodology for 30 incinerators.[9]

The available data appear to indicate that the majority of devices can meet a THC limit of 20 ppmv when operating under good combustion conditions (i.e., when CO is less than 100 ppmv). It appears, in fact, that many hazardous waste incinerators can typically achieve THC levels of 5 to 10 ppmv when operating generally at low CO levels. When incinerators emit higher THC levels, CO levels typically exceed 100 ppmv, indicative of poor combustion conditions. The available information on boilers and industrial furnaces is not quite as clear, however. Although the data base indicates that boilers burning hazardous waste can easily meet a THC limit of 20 ppmv, the Agency has obtained data on various types of

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[7] Hazardous waste incinerators have operated at CO levels exceeding 13,000 ppmv during trial burns that achieved 99.99% distribution and removal efficiency.

[8] See discussions in U.S. EPA, "Background Information Document for the Development of Regulations for PIC Emissions from Hazardous Waste Incinerators", December, 1988 (Draft Final Report).

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[9] Memorandum from Shiva Garg. EPA, to the Docket, entitled "Supporting Information for a GOP-Based THC Limit", dated October 20, 1988.

boilers burning various types of fossil fuels (not hazardous waste) that indicate that THC levels can exceed 20 ppmv when CO levels are less than 100 ppmv. See footnote 7. We are reviewing that data and obtaining additional information to determine if an alternative limit may be more appropriate for boilers. We specifically request comment on whether a THC concentration of 20 ppmv in fact represents good operating practice for boilers burning hazardous waste as the sole fuel or in combination with other fuels.

We also request comment on whether a THC concentration of 20 ppmv represents good operating practice for industrial furnaces. Preheater and precalciner cement kilns, for example, may not be able to readily achieve such a low THC concentration for the same reason that they typically cannot achieve CO levels below 100 ppmv. Normal raw materials such as limestone can contain trace levels of organic materials that oxidize incompletely as the raw material moves down the kiln from the feed end to the hot end where fuels are normally fired. Clearly, any THC (or CO) resulting from this phenomenon has nothing to do with combustion or hazardous waste fuel. Thus, an incinerator and a preheater or precalciner cement kiln with exactly the same quality of combustion conditions may have very different THC (and CO) levels. We request comment on: (1) The types of industrial furnaces for which a THC level of 20 ppmv is representative of good combustion conditions; (2) whether alternative THC limits may be more appropriate for certain industrial furnaces; and (3) whether an approach to identify a site-specific THC limit representative of good operating practices may be feasible (e.g., where THC levels when burning hazardous waste would be limited to baseline THC levels without burning hazardous waste). In support of comments, we request data on emissions of CO and THC under baseline and hazardous waste burning conditions, including characterization of the type and concentration of individual organic compounds emitted.

As mentioned previously, some data on CO and THC levels from industrial boilers burning fossil fuels (not hazardous waste) appear to indicate that THC levels can far exceed levels considered to be representative of good combustion conditions (20 ppmv) even though CO levels are less than 100 ppmv. See footnote 7. If it appears that this situation can, in fact, occur for particular devices burning particular

fuels, we would consider requiring both CO and THC monitoring for all such facilities irrespective of whether CO levels were less than 100 ppmv during the trial burn. Thus, under this scenario, the two-tiered CO controls proposed today would be replaced with a requirement to continuously monitor CO and THC for those particular facilities. We specifically request information on the types of facilities where THC levels may exceed 20 ppmv even though CO levels are less than 100 ppmv, and the need to continuously monitor THC for those facilities irrespective of the CO level achieved during the trial burn.

C. Implementation of Tier I and Tier II PIC Controls

1. *Oxygen and Moisture Correction.* The CO limits specified for either format are on a dry gas basis and corrected to 7 percent oxygen. The oxygen correction normalizes the CO data to a common base, recognizing the variation among the different technologies as well as modes of operation using different quantities of excess air. In-system leakage, the size of the facility and the type of waste feed are other factors that cause oxygen concentration to vary widely in flue gases. Seven percent oxygen was selected as the reference oxygen level because it is in the middle of the range of normal oxygen levels for hazardous waste combustion devices and it also is the reference level for the existing particulate standard for hazardous waste incinerators under § 264.343(c). The correction for humidity normalizes the CO data from the different types of CO monitors (e.g., extractive vs. in situ). Our evaluation indicates that the above two corrections, when applied, could change the measured CO levels by a factor of two in some cases.

Measured CO levels should be corrected continuously for the amount of oxygen in the stack gas according to the formula:

$$CO_c = CO_m \times \frac{14}{21-Y}$$

where CO_c is this corrected concentration of CO in the stack gas, CO_m is the measured CO concentration according to guidelines specified in appendix C, and Y is the measured oxygen concentration on a dry basis in the stack. Oxygen should be measured at the same stack location that CO is measured.

2. *Formats of the CO Limit.* The CO limits under Tier I and Tier II would be implemented under two alternative formats. The applicant would select the preferred approach on a case-by-case

basis. Under Format A, CO would be measured and recorded as an hourly rolling average. Under Format B, called the time-above-a-limit format, three parameters would be specified—a never-to-exceed CO limit, and a base CO limit not to be exceeded for more than a specified time in each hour.

In developing these alternative formats, EPA considered three alternate methods:

• A level never to be exceeded;
• A level to be exceeded for an accumulated specified time within a determined time frame; and
• An average level over a specified time that is never to be exceeded.

The first alternative is the simplest and requires immediate hazardous waste feed cutoff when the limit is exceeded, regardless of how long the CO levels remain high. Short-term CO excursions or peaks (a few minutes duration) are typical of combustion operations and can occur during routine operations; e.g., when a burner is adjusted. It is possible that during shutdown and start-up, the device may momentarily have high CO emissions. Since the total mass emissions under such momentary CO excursions is not high, a never-to-exceed limit would impede operations while providing little reduction in health risk.

The second alternative, allowing the CO level to exceed the limit for a specified accumulative time within a determined time frame (e.g., x minutes in an hour), solves the problem associated with the first alternative. The hazardous waste feed would not be cut off by a single CO peak of high intensity yet they would be restricted from operation with several short interval CO peaks, or a single long duration peak.

The third alternative, allowing the CO level never to exceed an average level determined over a specified time, also avoids the problem of shutting off the waste feed each time an instantaneous CO peak occurs. A time-weighted average value (i.e., integrated area under the CO peaks over a given time period) also provides a direct quantitative measure of mass emissions of CO. For this reason, the use of a rolling average is EPA's preferred format. A combination of the first and second alternatives, with provisions to limit mass CO emissions per unit time, its also proposed as an alternative format. This alternative CO format has been proposed to reduce the cost of instrumentation from that required to provide continuous rolling average CO values corrected for oxygen. This format may be particularly attractive to operators of small or intermittently

operated boilers. The CO monitoring system needed for the first alternative requires continuous measurement and adjustment of the oxygen correction factor and continuous computation of hourly rolling averages. The instrumentation costs of such a system, consisting of continuous CO and oxygen monitors with back-up systems, a data logger and microprocessor, could be up to $91,000 and would require increased sophistication and operating costs over simpler systems. The only instrumentation needed for the alternative time-above-the-limit format is a CO monitor and a timer that can indicate cumulative time of exceedances in every clock hour, at the end of which it is recalibrated (manually or electronically) to restart afresh. Oxygen also would not have to be measured continuously in this format; instead, an oxygen correction value can be determined from operating data collected during the trial burn. Subsequently, oxygen correction values would be determined annually or at more frequent intervals specified in the facility permit.[10] We have not limited the use of this alternative CO format to any size or to any type or class of device since we consider that this alternative format provides an equal degree of control of CO emissions to the rolling average format.

The alternative format would require dual CO levels to be established in the permit, the first as a never to exceed limit and the second a lower limit for cumulative exceedances of no more than a specified time in an hour. These limits and the time duration of exceedance would be established on a case-by-case basis by equating the mass emissions (peak areas) in both the formats so that the regulation is equally stringent in both cases. The PIC Background Document[11] for the incinerator rules provides the methodology and mathematical formulae showing how this can be done.

3. *Monitoring CO and Oxygen.* Compliance with the Tier I CO limit would require: (1) Continuous monitoring of CO during the trial burn and after the facility is permitted; (2) continuous monitoring of oxygen during the trial burn and, under the 60-minute

rolling average format, after the facility is permitted; and (3) measurement of moisture during the trial burn and annually (or as specified in the permit) thereafter. Compliance with the Tier II CO limits would require all the Tier I measurements and measurement of THC during the trial burn. Methods for measurements of CO and oxygen, (and THC) must be in accordance with the 3rd edition of SW–846, as amended. The methods are summarized in Appendix C and are discussed in more detail in "Proposed Methods for Stack Emissions Measurements of CO, O₂, THC, HCl, and Metals at Hazardous Waste Incinerators", U.S. EPA, July, 1989 (Draft Final Report). If compliance with the CO standard is not demonstrated during the DRE trial burn, the CO test burn must be under conditions identical to the DRE trial burn.

4. *Monitoring THC.* Under Tier II, THC would be monitored during the trial burn to ensure that the highest hourly average level does not exceed 20 ppmv. An exceedance of the THC limit would be linked to automatic waste feed cutoff. We believe that continuous THC monitoring should also be required over the life of the permit. This is because at high CO levels (e.g., greater than 100 ppmv) THC levels may or may not be high (e.g., greater than 20 ppmv). The concern is that, although THC levels during the trial burn may be less than 20 ppmv when CO exceeds 100 ppmv, operations over the life of the permit within the envelope allowed by the permit conditions may result in THC levels exceeding 20 ppmv. This concern was expressed by EPA's Science Advisory Board during its critique of the proposed PIC controls in the spring of 1989. EPA specifically requests comments on whether continuous monitoring of THC should be required over the life of the permit under Tier II.

EPA had developed specifications for THC monitoring (see appendix D) that would have required heated gas sampling lines and a heated flame ionization detector (FID) to keep as much of the THC in the vapor phase as possible. EPA reasoned that heated sampling lines were needed because the FID can detect THC only in the vapor phase—condensed organic compounds are not measured. Preliminary results of field testing of a hazardous waste incinerator conducted in July 1988 indicate that detected THC levels were 3 to 27 times greater with a heated FID system compared to an unheated system when CO levels ranged from 100 ppmv

to 2760 ppmv.[12] The total mass of volatile, semivolatile, and nonvolatile organic compounds was also quantified during those tests using the Level I screening procedure.[13] The results indicate that the THC levels detected by an unheated FID were much lower than the levels determined by the Level I screening procedure.

Based on cursory discussions in October of 1988 with several hazardous waste incinerator operators, we had believed that such heated systems were in use at some facilities. A follow-up written survey[14] indicated, however, that all of the six incinerator facilities surveyed that use a FID to monitor THC used a system that incorporated gas conditioning—condensate traps accompanying gas cooling systems. Thus, the Agency has not been able to document operating experiences with a heated (i.e., not conditioned) gas sampling system. Further, we understand that, based on EPA tests using a heated FID at an incinerator (see footnote 11) and comments made during the SAB review of the PIC controls, a heated FID system can pose a number of problems: (1) The sample extraction lines may plug due to heavy particulate loadings and condensed organic compounds; and (2) semi and nonvolatile compounds may adsorb on the inside of the extraction lines causing unknown effects on measurements.

Given these concerns about the technical feasibility of requiring the use of heated FIDs at this time, we are proposing that gas conditioning be allowed. Such conditioning could involve gas cooling to a level between 32 °F and the dew point of the gas and the use of condensate traps. To reduce operation and maintenance problems, the extraction lines and FID should probably still be heated.

Allowing gas conditioning in the interim until unconditioned systems can be shown to be practicable virtually precludes the use of the health-based alternative to assess THC emissions under the Tier II controls. This is because a large, undetermined fraction of THC emissions will be condensed to the trap and will not be reported by the FID. This is another reason that the

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[10] We believe that annual determinations of the oxygen correction factor will be appropriate in most cases because the concern is whether duct in-leakage has substantially changed over time. The fact that excess oxygen levels also change with waste type and feed rate should be considered in establishing the correction factor initially.

[11] U.S. EPA, "Background Information Document for the Development of Regulations for PIC Emissions from Hazardous Waste Incinerators," December, 1988 (Draft Final Report).

[12] U.S. EPA, "Measurement of Particulates, Metals, and Organics at a Hazardous Waste Incinerator", November, 1988, (Draft Final Report).

[13] The Level I screening procedure is described in "IERL–RTP Procedure Manual: Level I—Environmental Assessment," 2nd Edition, October 1978 (EPA 600/7–78–201). That procedure uses gravimetric and total chromatographical organic procedures to quantify the mass of semi and nonvolatile organic compounds.

[14] U.S. EPA, "THC Monitor Survey", June, 1989 (Draft Final Report).

Agency prefers the technology-based, 20 ppmv limit on THC as the Tier II standard.

Although a FID system monitoring a conditioned gas will detect only the volatile fraction of organic compounds (and, in some cases, only the nonwater-soluble volatile fraction), the Agency believes this is adequate for the purpose of determining whether the facility is operating under good operating conditions.[15] Available data indicate that when emissions of semi and nonvolatile organic compounds increase, volatile compounds also increase.[16] Thus, volatile compounds appear to be a good indicator for the semi and nonvolatile compounds that are often of greater concern because of their health effects. Given, however, that the good operating practice-based THC limit of 20 ppmv was based primarily on test burn data using heated (i.e., unconditioned gas) FID systems, the Agency considered whether to lower the recommended THC limit when an unheated system is used for compliance monitoring. As discussed above, limited available field test data indicated that a heated system would detect two to four times the mass of organic compounds than a conditioned system. We believe, however, that the 20 ppmv THC limit is still appropriate when a conditioned system is used because: (1) The data correlating heated vs conditioned systems are very limited; (2) the data on THC emissions are limited (and there apparently is confusion in some cases as to whether the data were taken with a heated or conditioned system); and (3) the risk methodology is not sophisticated enough to demonstrate that a THC limit of 5 to 10 ppmv using a conditioned system rather than a limit of 20 ppmv is needed to adequately protect public health.

The THC monitoring method proposed in Appendix D will be modified to allow an unheated, conditioned system and use of condensate trap(s) and other conditioning methods. The revised method will specify, however, that the

[15] We request comment on whether it would be practicable to develop a site-specific correction factor for monitoring with a conditioned gas system by monitoring with an unconditioned system as well during the trial burn. The ratio of the unconditioned system THC level to the conditioned system THC level could then be used to correct the conditioned system THC values over the life of the permit. This approach may not be practicable, however, for reasons including the fact that the waste burned during the trial burn for some facilities (e.g., facilities handling multiple wastes) may not represent, with respect to THC emissions, the waste that will be burned over the life of the permit.

[16] U.S. EPA, "Measurement of Particulates, Metals, and Organics at a Hazardous Waste Incinerator," November, 1988 (Draft Final Report).

sample gas may not be cooled below 32 °F.

5. *Compliance with Tier I CO Limit.* There are a number of alternative approaches to evaluate CO readings during the trial burn to determine compliance with the 100 ppmv limit including: (1) The time-weighted average CO level (or the average of the hourly rolling averages); (2) the average of the highests hourly rolling averages for all trial burn runs; of (3) the highest hourly rolling averge. The time-weighted average alternative provides the lowest CO level that could reasonably be used to determine compliance, and the highest hourly rolling average alternative provides the highest CO level that could reasonably be used. There may be other reasonable alternatives between these two extremes in addition to the one listed above.

We are proposing to use the most conservative approach to interpret trial burn CO emissions for compliance with the 100 ppmv Tier I limit—the highest hourly rolling average. (This approach is conservative because we are comparing the trial burn CO level to the maximum CO allowed under Tier I—100 ppmv.) We believe this conservative approach is reasonable given that compliance with Tier I allows the applicant to avoid the Tier II requirement to evaluate THC emissions to provide the additional assurance (or confirmation) that THC emissions do not exceed levels representative of good operating practice.

6. *Establishing Permit Limits for CO under Tier II.* The alternatives discussed above for interpreting CO trial burn data also apply to specifying the permit limit for CO under Tier II. For purposes of specifying a Tier II CO limit, however, the time-weighted average approach would be more conservative than the highest hourly average approach because it would result in a lower CO limit. We are proposing the conservative, time-weighted average approach for Tier II compliance because we are concerned that the highest hourly average approach may not be adequately protective. Although the highest hourly average (HHA) approach would be protective in theory because the applicant must demonstrate that the highest hourly average THC emissions do not exceed good operating practice-based levels, the HHA approach would allow the facility to operate continuously over the life of the permit at the highest CO levels that occurred during one hour of the trial burn.

We specifically request comments on how to interpret trial burn CO data to establish Tier II CO limits.

7. *Compliance with THC Limit of 20 ppmv.* The alternative approaches for determining compliance with the 20 ppmv THC limit under Tier II are identical to those discussed above for compliance with the Tier I CO limit. Again, we are proposing the most conservative approach—the highest hourly rolling average THC level during the (at a minimum) three test burns must not exceed 20 ppmv.

8. *Waste Feed Cutoffs.* In 1987, EPA proposed that if a device exceeded the CO limits an aggregate of 10 times per month, then the owner or operator must cease burning hazardous waste, notify the Regional Administrator, and not resume burning hazardous waste until reauthorized by the Regional Administration. Commenters complained that this proposed requirements was overly conservative. In response, EPA is considering deleting this restriction. We do not have data that indicate, nor are we aware of a good argument that would support, the need to limit cutoffs provided that combustion chamber temperatures are maintained at the levels that occurred during the trial burn for the duration of time that waste remains in the combustion chamber. We believe that maintaining temperatures will ensure that hydrocarbons emanating from the waste remaining in the combustion chamber after a cutoff are destroyed to levels that would pose acceptable health risk. To comply with this requirement, the permit must specify the minimum combustion chamber temperature occurring during the trial burn for devices that may leave a waste residue in the combustion chamber after waste feed cutoff (e.g., devices burning wastes that are solids). We note that, to comply with this requirement, owners and operators of boilers that comply with the proposed special operating conditions requisite to automatic waiver of the trial burn may be required to document minimum combustion chamber temperatures while complying with those special operating conditions. Moreover, we specifically request comment on the need to specify in the permit for all boilers and industrial furnaces, the minimum allowable combustion chamber temperatures based on the trial burn.

We note that adequate auxiliary burner capacity may be needed to maintain the temperature in the combustion chamber and allow destruction of the waste materials and associated combustion gases left in the

system after the waste feed is automatically cutoff. The safe start-up of the burners using auxiliary fuel requires approved burner safety management systems for prepurge, pilot lights, and induced draft fan starts. If these safety requirements preclude immediate start-up of auxiliary fuel burners and such start-up is needed to maintain temperatures (i.e., if the combustion chamber temperatures drop precipitously after waste feed cutoff), the auxiliary fuel may have to be burned continuously on "low fire" during nonupset conditions. After an automatic cutoff, hazardous waste should not be used as auxiliary fuel unless the waste is hazardous solely because it is ignitable, corrosive, or reactive, or it contains insignificant levels of toxic constituents.

We request comment on several alternative approaches to allow restart of the waste feed: (1) Restart after the hourly rolling average no longer exceeds the permit limit; (2) restart after an arbitrary 10 minute time period to enable the operator to stabilize combustion conditions; or (3) restart after the *instantaneous* CO level meets the hourly rolling average limit. This third alternative (i.e., basing restarts on the instantaneous CO levels) may be appropriate because it may take quite a while for the hourly rolling average to come within the permit limit while the event that caused the exceedance may well be over even before the CO monitor reports the exceedance. Under this alternative, the rolling average could be "re-set" when the hazardous waste feed is restarted either by: (1) basing the hourly rolling average on the CO level for the first minute after the restart (the same approach that would be used any time the waste feed is restarted for reasons other than a CO exceedance); or (2) assuming more conservatively given that CO levels may exceed the permit limit after the waste feed cutoff while residues continue to burn, that the hourly rolling average is equivalent to the permit limit (e.g., 100 ppmv) prior to the waste feed restart. A final refinement to this third alternative of allowing restarts after instantaneous CO levels fall below the permit limit would be not to reset the rolling average CO level and to require that the instantaneous CO level not exceed the (rolling average) permit limit (e.g., 100 ppmv) for the period after the restart and until the rolling average falls below the permit limit. Again, we specifically request comment on these alternative approaches to allow waste feed restarts.

When the automatic waste feed cutoff is triggered by a THC exceedance, we propose to allow a restart only after the hourly rolling average THC level has been reduced to 20 ppmv or less. We are not considering the options discussed above for restarts after a CO exceedance given that THC is a better surrogate for toxic organic emissions than CO. Thus, we believe that a more conservative waste feed restart policy is appropriate after a THC exceedance.

D. Miscellaneous Issues

1. *PIC Controls for Nonflame Industrial Furnaces.* We note that the PIC controls discussed above may not adequately control THC emissions from nonflame furnaces such as some electric arc smelters (in situations where, in fact, controls for emissions of organic compounds would apply (see discussion in section IX)). In nonflame devices where combustion is neither the primary mode of destruction of organic compounds in the waste, nor is used in an afterburner to burn hydrocarbon-laden off-gases from the thermal cracking of the waste, CO may not be an adequate surrogate to control THC emissions. That is, in nonflame devices, when CO emissions are low, THC emissions may be *high.* Thus, the Tier I CO limit of 100 ppmv may not be adequate to ensure that THC concentrations are low. Accordingly, we request comment on requiring continuous THC monitoring for nonflame devices to ensure that THC concentrations do not exceed the good operating practice-based level of 20 ppmv.

2. *Measuring CO and THC in Preheater and Precalciner Cement Kilns.* EPA has received comments that preheater and precalciner cement kilns typically have bypass ducts that by-pass the preheater or precalciner and carry kiln off-gases directly to the stack. Measuring CO and THC in the bypass duct rather than in the stack would provide data unaffected by CO and THC produced in the preheater or precalciner by coal combustion (in the precalciner) or by volatilizing trace levels of organic compounds present in the raw material. Testing of bypass gases in lieu of stack gases would be acceptable for compliance with the CO and THC controls provided that the CO and THC levels in the bypass gases are representative of the kiln off-gases (i.e., provided that CO and THC in the kiln off-gases are not stratified before entering the bypass).

3. *Feeding Waste in Cement Kilns by Methods Other Than Dispersion in the Flame at the Hot End.* The Agency is aware that several cement companies are investigating the feasibility of feeding solid hazardous waste into cement kilns and some facilities are already engaging in the practice. The solid materials are fed into the kiln system at locations other than the "hot" end of the kiln where liquid hazardous waste fuels and fossil fuels are normally fired. These practices may be an effective approach to both beneficially use the heating value in solid hazardous wastes and provide needed treatment capacity for such wastes. The Agency has not, however, conducted emission testing of cement kiln systems when burning solid hazardous wastes. Depending on the kiln system, location of the firing port, and type and quantity of hazardous waste fired, there is a potential concern for incomplete combustion of organic compounds in the waste. Conceivably, the waste may be fired into the systems at a point where adequate temperatures and residence time may not be provided to ensure adequate destruction. In addition, if a kiln system is equipped with a by-pass duct, combustion gases from burning the hazardous waste may be "short-circuited" and routed to the stack before adequate destruction can occur.

The proposed controls will effectively control emissions irrespective of how solid hazardous waste may be fired into kiln systems because the standards would apply to stack emissions. The question is, given that the Agency has not yet tested such operations, whether special requirements should be applied during interim status. We specifically request comment on the need for special controls during interim status when cement kiln systems feed hazardous waste at locations other than the hot end. Commenters should provide information on such practice, including data on organic emissions (e.g., DRE results, CO and THC concentration), and suggestions on appropriate interim status controls, if any are considered necessary (i.e., in addition to the interim status standards that would be applicable to all boilers and industrial furnaces, as discussed elsewhere in today's notice).

E. Implementation of PIC Controls During Interim Status

1. *Preferred Option.* We believe that the PIC controls can and should be applied as soon as possible for facilities in interim status. Thus, we are requesting comment on whether the following compliance schedule is reasonable. Within 12 months of promulgation of the final rule, boilers and industrial furnaces operating under interim status must install CO monitoring equipment meeting the performance specifications presented in

today's notice and determine compliance with the Tier I standard of 100 ppmv during a test burn representative of worst-case combustion conditions that will occur during interim status.[17] (Irrespective of which CO format is selected (i.e., hourly rolling average or time-above-a-limit) the maximum hourly average CO level during the test burn cannot exceed 100 ppmv under Tier I.) If CO levels do not exceed 100 ppmv, CO levels are limited during interim status to 100 ppmv.

If the maximum hourly average CO level exceeds 100 ppmv during the test burn, the owner or operator must, within 15 months of promulgation of the final rule, demonstrate that the maximum hourly average THC concentration does not exceed 20 ppmv during a test burn equivalent to the Tier I test burn, using THC monitoring equipment meeting the performance specifications presented in today's notice. If the THC concentration does not exceed 20 ppmv during the test burn, then, during the period of interim status, continuous monitoring of THC would be required to ensure that THC does not exceed 20 ppmv, and continuous monitoring of CO would be required to ensure that CO does not exceed the time-weighted average CO level that occurred during the test burn.

If the maximum hourly average THC level exceeds 20 ppmv during the test burn, the owner or operator must, within 18 months of promulgation of the final rule, modify operations as necessary and demonstrate in a subsequent test burn that THC concentrations do not exceed 20 ppmv, or cease burning hazardous waste and complete closure requirements.

We are considering an exception to the 20 ppmv THC limit, however, for cement kilns that can demonstrate that fuel-derived THC levels do not exceed the 20 ppmv limit even though stack gas concentrations may exceed the limit. The concern is that trace levels of organic compounds in the raw materials (e.g., limestone) can produce THC as the materials are gradually heated as they travel from the cold (i.e., feed) end of the kiln to the hot (i.e., fuel firing) end of the kiln. We specifically request comment on whether only fuel-derived THC should be considered for purposes of

compliance with the proposed THC limits. If so, we further request comment on whether the following approach is reasonable to identify fuel-derived THC. For cement kiln systems that burn or feed fuels only in the hot end of the kiln where the clinker product exits, the fuel-derived THC concentration could be determined by increasing excess oxygen levels much beyond normal levels (e.g., to 10%) and noting the minimum hourly average THC concentration that occurs. This is based on an assumption that, at high excess oxygen levels, fuel combustion efficiency will be maximized and fuel-derived THC will be virtually zero. Thus, residual THC would be attributable to organic matter in the raw materials. Accordingly, the allowable THC concentration would be 20 ppmv greater than the baseline nonfuel THC (i.e., the lowest hourly average concentration during the high excess oxygen tests). It is important to note that we are suggesting two limitations to this test: (1) only fossil fuel would be burned during the demonstration of nonfuel THC; and (2) the approach would be applicable to only those kiln systems that burn or feed fuels during the subject test in the hot end of the kiln (i.e., precalciner kilns and kilns feeding coal along with raw material in a preheater during the high excess oxygen test would not be eligible because incomplete combustion of the fuel could occur even at high excess oxygen levels).

Extensions of time may be allowable by the Regional Administrator on a case-by-case basis if circumstances beyond the owner or operator's control affect the facility's ability to comply with the above schedule.

2. *Alternate Option.* EPA is considering the following alternative approach to expedite implementation of the substantive PIC controls. Under this option, the owner or operator would be required within 18 months of promulgation of the final rule either to submit a complete Part B RCRA Permit Application, or to cease burning hazardous waste and complete closure requirements. This option has at least two major disadvantages. First, substantive controls on PIC emissions would not be applied until the Part B permit is issued. Second, the State or EPA permit officials may have higher priority facilities to handle and, thus, may not be able to process the applications for some time after they are submitted. The information provided in the permit may, in fact, become outdated before the permit officials start to process the application. In those situations, applicants may be required to

submit revised, updated permit applications.

III. Alternative Toxic Metal Standards

A. Overview

The 1987 proposed rule would have established a four-tiered standard to control emissions of arsenic, cadmium, hexavalent chromium, and lead. Tiers I through III would have established hazardous waste concentration, feed rate, and emission rate screening limits as a function of device type and thermal capacity. Tier IV would have provided for site-specific dispersion modeling to demonstrate that, when the screening limits were exceeded, emissions would, nevertheless, not pose unacceptable health risk. Although available data indicate that only the four metals specified of the 12 toxic metals listed in appendix VIII of part 261 are likely to be present in hazardous wastes burned in boilers and industrial furnaces at levels that pose unacceptable health risk, the permit writer would have to determine on a case-by-case basis that the other toxic metals were, in fact, not present at levels that could pose unacceptable risk.

Based on comments on the proposed rule and additional evaluation of the risk assessment approach, we are considering the following changes to the metals controls: (1) Expand the list of controlled metals to include all those toxic metals listed in appendix VIII of part 261 (except, for reasons discussed later, nickel and selenium); (2) establish the screening limits as a function of effective stack height, terrain, and land use rather than as a function of device type and capacity; and (3) provide the screening limit values in the Risk Assessment Guideline for Permitting Hazardous Waste Thermal Treatment Devices (RAG) rather than in the rule itself. The basis for these changes is discussed below.

B. Expanded List of Metals

Commenters noted that EPA's data base on the metals composition of hazardous waste is both limited and out of date in light of the Agency's efforts—and the statutory command—to require pretreatment of wastes that heretofore have been directly land disposed. Pretreatment is likely often to involve combustion. Thus, the other toxic metals could be found increasingly in hazardous wastes that are burned in boilers and industrial furnaces. In addition, if more toxic metal standards were included in the rule, the burden on permit writers would actually be reduced because explicit standards would be provided for all metals of

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[17] A single test burn consisting of 3 runs should be conducted to demonstrate compliance with all emissions standards—CO/THC, particulates, metals, and HCl. If simultaneous compliance testing is not practicable, however, the operating conditions of the test burns must be identical. We propose the CO and, if necessary THC, be monitored continuously for a minimum of 4 hours for each of three runs to provide a valid test burn. This time period is typical of that required for testing of destruction and removal efficiency.

potential concern. The length of permit proceedings would thus be shortened relieving to some extent regulatory burden as well.

We, therefore, are considering expanding the list of controlled metals to include: antimony, arsenic, barium, beryllium, cadmium, chromium (VI), lead, mercury, silver, and thallium. Thus, of the 12 metals listed in Appendix VIII, only selenium and nickel would not be controlled. We are not considering controls for selenium because the Agency has inadequate health data to establish a reference air concentration. Nickel would not be controlled because the two nickel compounds suspected at this time of being potential human carcinogens, nickel carbonyl and subsulfide, are not likely to be emitted from combustion devices, given the highly oxidizing conditions that exist in combustion devices. We note, however, that some industrial furnaces (e.g., electric arc smelters) do not use combustion to provide heat to drive process reactions. Such furnaces could conceivably emit the reduced, carcinogenic forms of nickel if present in the hazardous waste feed. We specifically request information on emissions of nickel carbonyl and subsulfide from such furnaces and suitable stack sampling and analysis procedures.

C. Revised Format for Screening Limits

In developing the proposed amendments to the incineration standards that the Agency plans to propose shortly, we developed Screening Limits for metals (and HCl and THC) as a function of effective stack height, terrain, and land use. As discussed above, we believe that basing limits on these parameters more directly ties the controls to the key parameters that affect dispersion of emissions and, ultimately, ambient levels. When developing the proposed Tier I through Tier III screening limits for boilers and industrial furnaces in 1987, we made a simplifying assumption that effective stack height correlated with thermal capacity (e.g., if the thermal capacity of one device was 10 percent greater than the thermal capacity of another, then the effective stack height was also 10 percent greater). This is not always true. Stack height is often more a function of the height of nearby buildings and surrounding terrain than the heat input capacity of the device. Thus, we are considering establishing for boilers and industrial furnaces the identical feed rate and emission rate Screening Limits we plan to propose for incinerators. The Screening Limits are presented in Appendix E, and the technical support

for the Limits is summarized in appendix F. We would also implement the metals controls for boilers and furnaces as we plan to propose in the incinerator amendments (i.e., risk from carcinogenic metals must be summed; risk from all on-site hazardous waste combustion facilities must be considered). See appendix G.

We note that, under this approach, screening limits provided by Tier I of the proposed rule would be deleted. Tier I established metals concentrations limits for hazardous waste in units of pounds of metal per million BTU of heat input to the device. Under that tier, the device was conservatively assumed to burn 100 percent hazardous waste (i.e., metals levels in hazardous waste burned in these devices are most always higher than in cofired fossil fuels). Under such a conservative assumption, we believe that few facilities burn hazardous waste with metals levels low enough to meet the Tier I limits. Note also that the feed rate Screening Limits provided by Appendices B–1 through B–4 of the proposed incinerator amendments would replace the Tier II limits originally proposed for boilers and industrial furnaces. The risk assessment methodology remains basically the same as proposed in 1987. EPA will, however, continue to accept comments on this methodology.

D. Screening Limits Provided by the Risk Assessment Guideline

We are considering providing the Screening Limits in the Risk Assessment Guidelines for Permitting Hazardous Waste Thermal Treatment Devices (RAG) rather than in the rule (i.e., the Code of Federal Regulations). This is consistent with the approach the Agency plans to propose for the incinerator amendments and would enable the Agency to update the limits as health effects data are revised and EPA's dispersion models evolve. Revisions to the RAG would be noticed in the Federal Register with the current edition noted.

However, EPA solicits comment on this and an alternative approach whereby the Agency would promulgate Screening Limits in the rule, as originally proposed for boilers and industrial furnaces. Providing the Screening Limits in the RAG has limitations. Our concern is that guidance documents do not carry the weight of a regulation—permit writers would be free to accept or reject the guidance (e.g., Screening Limits RACs, RSDs) and would be obligated to justify use and appropriateness of the guidance on a case-by-case basis. This could place a substantial burden on the

permit writer and result in inconsistent, and, perhaps, inappropriate permit conditions. If the Screening Limits are promulgated in the rule, EPA would then revise them by rulemaking if warranted by new information. In the interim, permit writers could apply stricter limits than contained in the rule (if the facts justify it) pursuant to the omnibus permit authority in section 3005(c)(3) (with notice and comment provided on the potential change during the permit proceeding).

E. Implementation of Metals Controls During Interim Status

1. *Preferred Option.* We are considering a significant modification to the proposed compliance schedule. Under this alternative, interim status sources would determine compliance with metal (and HCl) Screening Limits within 12 months of promulgation of the final rule. If a source cannot comply with the Screening Limits within the initial 12 months, then the owner or operator must: (1) Within 15 months of promulgation, demonstrate compliance with the reference air concentrations for noncarcinogenic metals and the 10^{-5} risk level for carcinogenic metals using dispersion modeling; or (2) within 24 months of promulgation, either modify the facility and demonstrate compliance or complete closure requirements with respect to hazardous waste burning. The Regional Administrator could extend the compliance period if the owner or operator can show inability to make required modifications because of situations beyond its control (e.g., unavailability of equipment).

2. *Alternative Options.* In addition, EPA is considering the following alternative interim status requirements, similar to those for particulates, to bring sources into compliance with the metals (and HCL) standards. The first would require facilities that cannot demonstrate compliance within 12 months of promulgation to submit a compliance plan within 15 months of promulgation which assures expedient compliance (i.e., within 12 months of EPA approval). The last alternative would require the source to submit a complete Part B RCRA Permit Application, draft trial burn plan, and site-specific risk assessment as applicable, within 18 months of promulgation; or implement closure requirements within 18 months of promulgation. EPA is requesting comments on all three alternatives for implementing metals and HCl standards.

IV. Alternative Hydrogen Chloride Standards

EPA is also considering an alternative approach to the proposed hydrogen chloride (HCl) standards. As discussed above for the metals standards, we are considering: (1) Establishing the screening limits as a function of effective stack height, terrain, and land use rather than device type and capacity; and (2) providing the screening limit values in the RAG rather than in the rule itself. (The HCl controls would also be implemented during interim status like the metals controls.) The bases for these changes are identical to those discussed above for metals.

V. Revisions to the Proposed Small Quantity Burner Exemption

A. Summary

EPA proposed to exempt facilities that burn de minimis quantities of their own hazardous waste because, absent regulatory control, the health risk posed by such burning would not be significant. Eligibility for the exemption would be based on the quantity of waste burned per month, established as a function of device type and thermal capacity. In order to be exempt, in addition to restrictions on quantity of waste burned, facilities would be required to notify the Regional Administrator that they are a small quantity burner, the maximum instantaneous waste firing rate would be limited to one percent of total fuel burned, and dioxin-containing acutely toxic wastes could not be burned. See proposed § 266.34–1(b).

We are considering several revisions to this proposed provision. Rather than establishing exemption quantities as a function of device type and capacity, we are considering using effective stack height. Also, several improvements could be made in the risk assessment methodology and the procedures for handling multiple devices could be made less arbitrary to reduce over-regulation. The basis for these changes is discussed below.

B. Revised Format for Exempt Quantities

Under this alternative approach, exempt quantities would be established

as a function of effective stack height rather than device type and thermal capacity (see Table 1). We believe this approach is preferable for the reasons discussed above. We note that we are not suggesting to include the two variables used for the metals and HCl limits, terrain type and land use classification, in establishing revised exempt quantities. Rather, the revised quantities are based on assumptions of terrain and land use that result in the lowest (i.e., most conservative) exempt quantities. We believe that this conservative approach is appropriate given that there would be no EPA or State agency oversight of an operator's determination of his terrain and land use classification.

TABLE 1.—EXEMPT QUANTITIES FOR SMALL QUANTITY BURNER EXEMPTION

Terrain-adjusted effective stack height of device (meters)	Allowable hazardous waste burning rates (gallons/month)
0 to 3.9	0
4.0 to 5.9	13
6.0 to 7.9	18
8.0 to 9.9	27
10.0 to 11.9	40
12.0 to 13.9	48
14.0 to 15.9	59
16.0 to 17.9	69
18.0 to 19.9	76
20.0 to 21.9	84
22.0 to 23.9	93
24.0 to 25.9	100
26.0 to 27.9	110
28.0 to 29.9	130
30.0 to 34.9	140
35.0 to 39.9	170
40.0 to 44.9	210
45.0 to 49.9	260
50.0 to 54.9	330
55.0 to 59.9	400
60.0 to 64.9	490
65.0 to 69.9	610
70.0 to 74.9	680
75.0 to 79.9	760
80.0 to 84.9	850
85.0 to 89.9	960
90.0 to 94.9	1,100
95.0 to 99.9	1,200
100.0 to 104.9	1,300
105.0 to 109.9	1,500
110.0 to 114.9	1,700
Greater than 115.0	1,900

C. Improvements in the Risk Assessment Methodology

The changes in the risk assessment methodology used to develop the revised exempt quantities presented in Table 1 include: (1) Consideration of the risk from emissions of total hydrocarbons (THC) rather than only those products of incomplete combustion (PICs) quantified during EPA's field testing program; and (2) a carcinogenic potency of $Q_1* = 0.07$ (that translates to a unit risk of 2.0×10^{-5}) was assumed for the THC rather than a Q_1* of 1.0 for PICs. The revised Q_1* is based on the average weighted unit risk developed to control THC emissions (see discussion above under alternative CO standards) which was doubled to account for the fact that THC emissions will likely be more toxic at the conservatively assumed 99 percent DRE than at the 99.99 percent DRE measured during the tests.

We are considering this change because we are concerned about a nonconservative feature of the PIC/POHC ratio used to estimate the risk from PIC emissions in establishing the proposed exempt quantities. The PIC/POHC ratio considers only those PICs for which emissions have been quantified. As discussed elsewhere in this Notice, organic compounds, other than those specifically quantified to date, are emitted from these combustion devices, and some of those compounds are undoubtedly toxic. Thus, we believe it is prudent (conservative) to consider THC rather than just quantified PICs in this analysis.

A detailed description of the methodology used to calculate the revised exempt quantities is available in the docket for public review and comment.[18]

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[18] U.S. EPA, "Analysis for Calculating a *de Minimis* Exemption for Burning Small Quantities of Waste in Combustion Devices", August 1989.

The revised approach uses the following equation to calculate exempt quantities:

$$\text{Allowable THC Mass Emission Rate} = \text{THC Emis. Conc.} \left(\text{Waste quantity} \times \frac{\text{Volume of combustion gas}}{\text{Mass of waste}} \right)$$

where:

Allowable THC Mass Emission Rate means the back-calculated, risk-based THC emission rate in grams/second, assuming an acceptable MEI risk of 10^{-5} and a THC unit risk of 2.0×10^{-5} ($Q^* = 0.07$), and using the conservative dispersion coefficients discussed above.

THC Emission Concentration means the THC emissions concentration in grams/liter (g/l) for an assumed destruction and removal efficiency of 99 percent. The value used is 15,000 ppm converted to g/1 based on field data that show THC concentrations range from 0 to 142 ppm when devices achieve 99.99 percent DRE and an assumption that the levels would be 100 times higher at 99 percent DRE.

Waste Quantity means maximum allowable waste quantity in pounds/second.

Volume of Combustion Gas/Mass of Waste means the empirically-derived relationship between combustion gas volumes and quantity of waste burned. That value is 200 dscf/lb of wastes.

The above equation was solved for waste quantity per unit of time for a range of Allowable THC Mass Emission Rates corresponding to the range of effective stack heights. Those values were then converted to gallons/month assuming the waste has a density of 8 lb/gallon.

D. Multiple Devices

Under this revised approach, the exempt quantities for a facility with multiple stacks from boilers or industrial furnaces burning hazardous waste would be limited according to the following equation:

$$\sum_{i=1}^{n} \frac{\text{Actual Quantity Burned}_i}{\text{Allowable Quantity Burned}_i} \leq 1$$

where:

N means the number of stacks

Actual Quantity Burned$_i$ means the waste quantity per month burned in device with "i"

Allowable Quantity Burned$_i$ means the maximum allowable exempt quantity for stack "i" from Table 1.

For example if a site had two devices with effective stack heights (ESH) of 30 and 10 meters, the following equation would hold:

$$\frac{X}{130} + \frac{Y}{33} < 1$$

Where:

130 and 33 are the exempt quantities from Table 1 for stack heights of 30 and 10 meters, respectively

X is the waste quantity burned in the device with the 30 meter stack

Y is the waste quantity burned in the device with the 10 meter stack

In this example, if Y is burning 15 gallons/month, then X could burn no more than 84 gallons/month.

VI. Definition of Indigenous Waste That Is Reclaimed

In the May 6, 1987, notice, the Agency solicited comment on the issue of when a hazardous waste that was burned exclusively for material recovery might be considered to be "indigenous" to the industrial furnace in which it was being burned. See 52 FR 16990–991. The significance of being indigenous is that the material would cease being a solid and hazardous waste upon being inserted into the industrial furnace. At that point, it would be an in-process material and no longer discarded. The industrial furnace thus would not be subject to the proposed emission standards. In addition, any residues from burning would not be subject to the derived-from rule in § 261.3(c)(2) because such residues would not derive from management of a hazardous waste.

The Agency proposed that a waste be considered indigenous if it was generated and burned in the same type of industrial furnace. In addition, scrap metal would be considered indigenous to any secondary smelting furnace, and lead acid battery plates and grids would have been considered to be indigenous to secondary lead smelting furnaces.

Commenters almost unanimously favored some type of indigenous test, but disagreed on its precise scope, offering a variety of suggestions. After analyzing these comments, the Agency solicits comment on a different option which incorporates features from the Agency's initial proposal, as well as proposals received from previous public comments.

As summarized below, the test for when a waste is indigenous to an industrial furnace would vary according to the source of the waste, and, in some cases, whether the industrial furnace is a primary or secondary furnace (whether it processes chiefly ores or secondary materials such as scrap metal).

A. Industrial (Smelting) Furnaces in the Standard Industrial Code (SIC) 33 Burning Wastes From SIC 33 Processes

Standard Industrial Code 33 encompasses all Primary Metal Industries including iron and steel manufacturing and processing, and iron and steel foundries; and primary and secondary nonferrous metal manufacturing and processing according to the 1972 Edition of the SIC. Commenters suggested and the Agency tentatively agrees, that these processes are sufficiently interrelated that secondary materials going from one process to another within this SIC code (33) should be generally considered indigenous.

However, situations may arise where wastes from SIC 33 processes are burned in SIC 33 furnaces for the objective of waste treatment by destroying unrecyclable toxic constituents (that would be "discarded materials" within the meaning of RCRA 1004(27)). Therefore, to be considered indigenous, the only unrecyclable toxic constituents (i.e., compounds listed in Appendix VIII 40 CFR part 261) the waste could contain are those that are found in the virgin material customarily processed (provided that the concentration in the waste is not significantly higher than concentrations in the raw material), and those that are present only in insignificant amounts if not normally found in the virgin material customarily processed in industrial furnaces. In the Agency's opinion, an insignificant amount of unrecyclable constituents would be 500 ppm of total nonindigenous toxic organics or 500 ppm of total nonindigenous toxic metals (or inorganic toxics) above the levels of those toxic constituents found in the virgin material customarily processed. In the EPA's judgment, this concentration level represents a concentration of material far exceeding minimal trace levels (generally measured in single digit parts per million (ppm) or tens of ppm). This level of a hazardous constituent could create an incremental health risk if burned inefficiently, or with inadequate

emission controls, and, moreover, indicates that the objective of burning is waste treatment as opposed to reclamation.

The following example illustrates this test as to whether a waste is indigenous:

• A steel production facility sends its electric arc furnace emission control dust (Hazardous Waste K061) to a zinc smelting furnace for zinc recovery. This waste contain 500 ppm and 2,100 ppm of cadmium and lead respectively. Assume for purposes of this example, lead and cadmium are also found in zinc ore concentrates at levels of 200 ppm and 2,000 ppm respectively. Lead and cadmium are not recycled—they do not partition primarily to a product.

As a result, K061 would be considered to be indigenous because steel production and zinc smelting are both SIC 33 activities, and these dusts are high in zinc content, indicating that legitimate material recovery is occurring. This is true even though the waste contains unrecyclable toxic constituents in significant concentrations.[19] However, these constituents are also present in significant concentrations in virgin ore concentrates customarily processed by zinc smelting facilities. The waste contains a total of 400 ppm (300 ppm lead and 100 ppm cadmium) of toxic metals above the virgin material, and, thus, does not exceed the 500 ppm limit.

B. SIC Code 33 Industrial Furnaces Burning Wastes Generated by Process Other Than SIC 33

When an SIC Code 33 industrial furnace burns a material generated by a process other than SIC 33, there is no longer such similarity of process and material that transfer of wastes should be considered *prima facie* indigenous. There is also a greater likelihood that the purpose of burning really is waste treatment. This is because the materials being burned are more likely to contain high concentrations of unrecyclable, nonindigenous toxic constituents (i.e., toxic constituents not found in the virgin material customarily burned in the industrial furnace) because of the dissimilarity of the generating and recovery processes. Consequently, the Agency is tentatively of the view that a material generated by a non-SIC code 33 process burned in an SIC 33 code furnace would only be indigenous to that furnace if it contained unrecovered toxic constituents present in the waste in insignificant concentrations, i.e., less than 500 ppm for total Appendix VIII toxic organic compounds and 500 ppm

[19] Note: Some zinc smelters may be capable of also recovering cadmium and lead.

for total unreclaimed Appendix VIII toxic metals.

The following example illustrates operation of this principle. An electroplating facility sends its wastewater treatment sludge (Hazardous waste F006) to a primary copper smelter for recovery of copper. The electroplating sludge also contains thousands of parts per million each of cyanide, cadmium and lead which are not beneficially recovered in the smelting process. The electroplating sludge would not be considered indigenous to the primary copper smelter. The sludge is not from a SIC 33 process and contains substantial concentrations of unrecovered toxic constituents which are discarded by the process. The environmental concern is that, due to the presence of these nonindigenous toxics, the waste poses risks—in the transport, storage and burning phase as well as residuals—that are different than those posed by the raw materials customarily burned in the devices.

C. Secondary Smelting Furnaces

As the Agency noted at proposal, a somewhat broader notion of indigenous material is needed for secondary smelting furnaces because these furnaces normally accept secondary materials (principally scrap metal) as their principal feed material. Thus, the Agency would consider any scrap metal indigenous to a secondary smelter. Further, the Agency would consider any material with recoverable metal values indigenous to a secondary smelter providing that the materials do not contain high concentrations of nonrecovered organics or significant concentrations of metals or inorganics not found in the non-hazardous secondary materials utilized as feed by secondary smelting furnaces. To be considered indigenous, these materials need not be generated by an SIC 33 process. This type of comparison, rather than a comparison just with virgin ore concentrate utilized by primary smelters, could be appropriate given that secondary smelting furnaces are different types of furnaces than primary furnaces, and given further that secondary smelters have traditionally processed a wider range of materials than primary smelters.

In addition, for secondary lead furnaces, the Agency would view items listed in Table 2 as indigenous. These are normal feed materials to secondary lead furnaces. Also, any lead-bearing waste from manufacture of batteries would be considered indigenous to a secondary lead smelter. These materials are likewise routinely sent to lead

smelters for lead recovery and are within any normal contemplation of the term indigenous. EPA is specifically requesting comment as to whether this list is complete.

TABLE 2—MATERIALS INDIGENOUS TO SECONDARY LEAD FURNACES WHEN GENERATED BY PRIMARY AND SECONDARY LEAD FURNACE OR LEAD BATTERY MANUFACTURING OPERATIONS

Acid dump/fill solids
Baghouse dusts
Scrap grids
Scrap batteries
Scrap lead oxide
Dross
Scrap plates
Slurry and slurry screenings
Sump mud
Lead acetate from laboratory analyses
Acid filters
Baghouse bags
Scrap battery cases, covers, vents
Charging jumpers and clips
Disposable clothing (coveralls, aprons, hats, gloves)
Floor sweepings
Air filters
Pasting belts
Platen abrasive
Respirator cartridge filters
Shop abrasives
Stacking boards
Waste shipping containers (cartons, plastic bags, drums)
Water filter media
Paper hand towels
Cheesecloth from pasting rollers
Pasting additive bags
Wiping rags
Contaminated pallets

VII. Conforming Requirements

EPA is considering a proposal to amend to the incinerator standards of subpart O, part 264 and part 270. Many of the boiler and furnace requirements proposed in 1987 were taken, from the planned changes to the incinerator standards. Thus, all revisions that ultimately are proposed to such incinerator standards also will be proposed, as part of that notice, to apply to boilers and industrial furnaces.

VIII. Halogen Acid Furnaces

On March 31, 1986, Dow Chemical Company petitioned EPA, in accordance with the provisions of 40 CFR 260.20, requesting EPA to designate their halogen acid furnaces (HAFs) as industrial furnaces under 40 CFR 260.10. EPA then proposed to grant the petition in the May 6, 1987, proposal.

EPA received comments and additional information on the petition and, as a result, plans to repropose this rule change as part of the proposed amendments to the hazardous waste incinerator standards. A detailed discussion will be provided in that preamble. However, a brief summary of the changes EPA is considering are listed below:

1. The halogen acid concentration of the halogen acid solutions produced will be lowered to three percent from six percent.

2. Fifty percent of the acid must be used onsite. This condition did not appear in the original proposal.

3. EPA proposes to allow the burning of offsite waste providing it is indigenous to Chemical Production (i.e., generated by Standard Industrial Classification 281 or 286).

4. The waste being burned must contain at least 20 percent halogens by weight.

5. Waste fed to HAFs would be listed as inherently waste-like under 40 CFR 261.2(d) to ensure they remain regulated.

EPA is considering the imposition of some or all of the above changes, and, although we will not consider comments on these issues received in response to today's notice, we will request comments on these alternatives when they are proposed as a part of the amendments to the incinerator standards.

IX. Regulation of Smelting Furnaces Involved in Materials Recovery

In the May 6, 1986, proposal, EPA proposed regulatory standards for smelting furnaces burning metal-bearing hazardous waste to recover metals that were the same as the standards for furnaces and boilers burning hazardous wastes for energy recovery. As discussed in section VI above, smelters burning nonindigenous waste would be subject to full regulation.

We have reconsidered how the proposed rules should apply when permitting smelters and request comment on the following approach. We do not believe it is appropriate to apply the organic emissions controls (i.e., destruction and removal efficiency (DRE), and carbon monoxide emissions standards) to smelters that burn waste containing *de minimis* levels of toxic organic constituents. We believe that such *de minimis* levels could be based on the quantity levels established for the small quantity burner exemption. See table 1 of section V of this notice. To establish *de minimis* feed rates of total organic constituents for smelters, the small quantity burner exemption quantities in gallons per month could be

converted to pounds per month assuming a waste density of 8 lb/gallon. Burning/processing these feed rates of toxic organic constituents absent the DRE and CO controls should be protective given that the exempt quantities were calculated assuming a 99% DRE and considered the health risk from total hydrocarbon emissions (i.e., unburned organic compounds in the waste and products of incomplete combustion). In order to simplify compliance monitoring and assure adequate conservatism when not making a DRE determination, we believe total organic carbon (TOC) could be used as an indicator for toxic organic constituents. A TOC measurement is conservative because it measures all organic compounds, not just toxic (appendix VIII) constituents.

We do not believe a similar, purely health-based approach is appropriate to determine when the proposed metals controls should apply when permitting smelters. Rather, we believe that the metals controls should apply only when the hazardous waste significantly affects emissions of toxic (appendix VIII) metals. If we were to regulate metals emissions when burning/ processing hazardous waste even though those emissions are not adversely affected, we would create an economic disincentive to smelting hazardous waste. Smelters burning hazardous wastes could be regulated more stringently with respect to the same metals than smelters processing ores even though metals emissions were identical. In that situation, ores could displace the hazardous waste with no environmental benefit. To determine if the hazardous waste significantly affects toxic metals emissions, the applicant would need to demonstrate that either: (1) The concentration of each regulated toxic metal in the hazardous waste is not significantly greater than the average level of the metal in normal, nonhazardous waste feedstocks; or (2) the emissions of each regulated toxic metal present in the hazardous waste is not significantly greater than baseline emissions when hazardous waste is not processed. An appropriate statistical test would be used in either case to determine if an increase were significant. The proposed metals controls would apply to each metal for which the applicant could not make a successful or significant increase demonstration.

We specifically invite comment on these approaches to determine the applicability of the proposed controls on organic and metals emissions.

X. Status of Residues from Burning Hazardous Waste

Under the Agency's existing regulations, wastes that are derived from the treatment of listed hazardous wastes are also considered to be hazardous unless and until they are delisted. See 40 CFR 261.3 (c)(2) and (d)(2). Thermal combustion of hazardous waste, no matter the type of device in which it occurs or the purpose of burning, is a type of treatment. Accordingly, under the Agency's existing rules, residues from thermal combustion of listed hazardous waste are considered to remain the listed hazardous waste until delisted.

When the device burning hazardous waste is a boiler burning primarily coal or other fossil fuels, an industrial furnace processing ores or minerals (e.g., light-weight aggregate kilns), or a cement kiln, a further consideration enters: the applicability of the so-called Bevill amendment (which requires a special study before subtitle C regulations can be imposed). (See RCRA section 3001(b)(3)(A) (i)–(iii).) The Agency has stated previously that when these devices burn hazardous waste fuels: (1) Residues of industrial and utility boilers burning at least 50 percent coal remain within the Bevill amendment; (2) residues of boilers burning oil or gas with other materials are not within the Bevill amendment; and (3) residues of industrial furnaces (processing ores or minerals) and cement kilns burning hazardous waste fuel remain within the Bevill amendment. See generally 50 FR 49190 and n. 87–89 (Nov. 29, 1985). The underlying principle for these determinations was that residues would remain within the Bevill amendment if the character of the residual is determined by the Bevill material (i.e., coal, ores or minerals, or cement aggregate) being burned or processed. Thus, any residues that come from burning or processing the Bevill material requires a special study before it could come under Subtitle C regulation and so would remain exempt.

In a later proposal, the Agency suggested a refinement of these positions to address residues from industrial furnaces processing ores or minerals and cement kilns burning nonindigenous hazardous waste for materials recovery. See 52 FR 17012–013 (May 6, 1987). Under that proposal, such residues would remain within the Bevill Amendment provided that at least 50 percent of the raw material feed to the device was a virgin ore or mineral. In addition, residues from devices burning

hazardous waste for the purpose of destruction (i.e., for neither energy nor materials recovery) would be outside of the Bevill amendment.

We have further evaluated these interpretations in light of our stated principle: residues from coburning hazardous waste and Bevill raw materials should remain within the Bevill amendment provided that the character of the residues is determined by the Bevill material (i.e., the residue is not significantly affected by burning the hazardous waste). (We explain below more precisely what we mean by these terms.) We believe that our present data base for making these interpretations is not sufficient to ensure that, in every case, the residue would not be significantly affected by the hazardous waste.[20][21] Further, we have reconsidered whether the May 6, 1987, proposed interpretation that residues generated by the subject devices when burning waste for destruction are not within the Bevill amendment is consistent with the stated principle.

Thus, we are today taking two steps to address these issues. We are specifically requesting data on the levels of Appendix VIII toxic compounds in residues from Bevill devices generated with and without burning or processing hazardous waste. If adequate data are available, we may be able to make generic determinations in some situations that the cogenerated residue is not significantly affected by burning or processing the hazardous waste, and thus, remains within the Bevill amendment. Given that the effect of the hazardous waste on the cogenerated residue may be a function of site-specific factors (see discussion below), it may be difficult to make generic determinations in many cases. At a

minimum, however, we would like to be able to establish generic baseline levels of toxic compounds in the residues that reflect the composition of residues *without* burning or processing hazardous waste. If baseline levels can be established, each owner or operator would need only to determine the levels of toxic compounds in the cogenerated residue and compare them to the established baseline levels.

In addition, in the absence of data at this time to make supportable determinations, we are proposing to require case-by-case determinations of the effect of coburning on residuals. We believe that today's proposed approach is preferable to that proposed on May 6, 1987, because today's approach would focus on the residues actually generated rather than on the purpose for which the hazardous waste is burned. A drawback to the May 6 proposal is that it would not ensure that the residues generated continue to have the character that was the basis for the statutory exclusion pending completion of the Section 8002 studies. In addition, the Agency's historic approach to the issue of cogenerated residues has been to focus on the character of the residues to ascertain what determines their character—the Bevill material or the hazardous waste being burned. See 50 FR 49190, n. 87 (November 29, 1987). The Agency also solicited comment on this approach— focused on what actually is in the residues—in the May 6 proposal. See 52 FR 17013. The statute itself does not directly specify that the purpose of the burning is a relevant criterion, but rather states that certain types of waste are excluded from subtitle C pending completion of studies. The approach we are proposing today is designated to ensure that the residues remain these types of wastes in order for the exclusion to continue to apply. Accordingly, assuming that it is feasible to implement on a case-by-case basis an approach that focuses on the type of residue generated by coburning situations, we believe that this is the preferable approach. We elaborate below on how this determination could be made.

As a preliminary matter, however, we note that it may be cumbersome to make case-by-case determinations on the effect of coburning (and coprocessing) on residues. As discussed below, sufficient sampling and analyses would be required of large volume residuals that often have levels of constituents that vary widely on a daily (or hourly) basis. Thus, we would prefer to obtain the data necessary to make generic determinations. Many factors, however,

could have an impact on whether the residues from a particular device (e.g., cement kiln, light-weight aggregate kiln, boiler) are affected by coburning. For example, the following factors could affect partitioning of metals to residues rather than to product or flue gases:[22] (1) Waste feed rate; (2) levels and volatility of metals in the waste; (3) physical form of the waste (liquid versus solid); and (4) waste feed system. Similarly, the following factors could affect levels of organic constituents in the residues attributable to burning hazardous waste: (1) Waste feed rate: (2) levels and types (e.g., difficulty of destruction, by-products formed) of toxic organics in the hazardous waste; (3) physical form of the waste; and (4) waste feed system. In the absence of a sufficient data base, and due to the cost of developing the extensive data base needed to make a generic determination, we believe we must rely on case-by-case determinations. We believe that, in the interim and absent documentation on impacts of coburning and coprocessing on residuals, the alternative to case-by-case determinations could be to exclude such residuals from the Bevill Amendment.

We discuss below how we propose to implement the stated principle on application of the Bevill amendment— coburning residues should remain within the exclusion provided that the character of the residues is not significantly affected by the hazardous waste.

A. *The Device Must Be a Bevill Device*

Congress intended to exclude, until further studies were completed, residues from: (i) Devices that burn primarily fossil fuel; (ii) industrial furnaces processing ores or minerals; and (iii) cement kilns. Thus, to be eligible for exclusion from subtitle C regulation under the Bevill amendment, the residue must be generated from a boiler burning primarily coal,[23] an industrial furnace processing primarily ores or minerals (since otherwise residues could not be said to come from processing ores and minerals, but rather from processing some other material), or a cement kiln processing primarily raw materials. To implement objectively the provision that, to be eligible for the Bevill exclusion of residues, the device must

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[20] As noted above, the Agency also found that residues from cofiring oil and gas with hazardous waste fuel were not within the scope of the Bevill amendment because te residues' character would be determined by firing hazardous waste. 50 FR 49190. Thus, all residuals from burning hazardous waste with gas in a boiler and bottom ash and fly ash from burning hazardous waste with oil in a boiler are outside of the Bevill amendment. This is because gas-fired boilers generate virtually no residues and oil-fired boilers generate little bottom or fly ash. In words of the statute, such residues result primarily from burning hazardous waste fuel, not from burning fossil fuels. This determination is not being reopened for public comment and the Agency is mentioning it only to accurately describe its past actions.

[21] See Memorandum to the Docket from Dwight Hlustick, EPA, dated March 11, 1988 summarizing available data on levels of toxic compounds in cogenerated cement kiln dust, light-weight aggregate kiln emissions control scrubber water and settling pond residue, and coal-fired boiler collected fly ash, and baseline (without burning/processing hazardous waste) levels in cement kiln dust, and coal-fired boiler collected fly ash.

[22] We note that flue gases would be subject to regulation irrespective of the applicability of the Bevill Amendment to residues, unless the device is an industrial furnace processing indigenous waste solely for reclamation.

[23] Residues from gas and oil fired boilers are not within the scope of the Bevill amendment as discussed above in the text.

burn primarily Bevill material, we would require that a boiler must burn at least 50 percent coal, an industrial furnace [24] must process at least 50 percent ores or minerals, and at least 50 percent of the feedstock to a cement kiln must be raw materials. This requirement also confirms the Agency's long-standing interpretation that the Bevill amendment applies only to primary facilities and not to secondary facilities such as, for example, secondary smelters.[25]

B. Determining if the Residue's Character is Influenced by the Burning of Hazardous Waste

As discussed above, residues from cofiring hazardous waste with gas or oil in a boiler would remain outside of the Bevill amendment. For cogenerated residues in other situations, we are proposing to require a case-by-case determination as to whether the hazardous waste burning or processing significantly affects the character of the residue with respect to inorganic and organic toxic (i.e., appendix VIII) contaminants.[26]

To determine whether there is a significant increase in the level of an appendix VIII compound in the cogenerated residue compared to the baseline residue generated without burning or processing hazardous waste, a number of questions must be addressed, including: (1) What constitutes a representative baseline residue (e.g., considering type, sources, and feed rates of normal—i.e., nonwaste—feedstocks and fuels): (2) what constitutes a representative cogenerated residue (e.g., considering composition, physical form, and feed rate of hazardous waste); (3) what sampling scheme is needed to ensure representative samples for comparison between baseline and cogenerated residues; and, ultimately, (4) what constitutes a significant increase in contaminant levels. We believe that the Agency needs to answer the first and fourth questions, as discussed below. The second and third questions, however, are typically site-specific and, thus, can best be addressed by the owner or operator. The owner and operator should use their best judgment to obtain analyses of representative

samples. The approach should be based on, and be consistent with, representative sampling protocols in SW-846, and must be documented by recordkeeping. The Agency solicits comment on how frequently and under what conditions residues should be retested over time.

We note that it may not be necessary to obtain data on a site-specific bases. Rather, owners and operators may choose to use data from other representative facilities to make generic determinations for particular devices under particular conditions (see discussion above on factors that can affect generic determinations).

We discuss next how we believe the other two questions should be addressed: How to establish baseline concentrations, and what constitutes a significant increase in contaminant levels.

1. *Baseline Concentrations.* As discussed above, we prefer to establish generic baseline residue concentrations of toxic (appendix VIII) compounds. We would use the limited available data (primarily on coal-fired boiler ash and cement kiln dust) and additional data that may be forthcoming from the regulated community. If baseline concentrations were established on a site-specific basis, facilities cofiring with, for example, coal containing unusually high (for coal) levels of metals would be allowed to cogenerate residues (within the scope of the Bevill amendment) that had higher metals levels than residues cogenerated at another like facility cofiring coal with unusually low (for coal) metals levels. Thus, facilities burning relative "clean" fuels (and processing relatively clean raw materials) would be at a disadvantage.

We specifically request information on concentrations of appendix VIII toxic constituents in baseline (and cogenerated) residue. In addition, we request comments on how to established generic baseline concentrations considering such issues as what concentration for a given toxic constituent (within the range of values for a particular residue generated by a particular type of device) should be used as the generic value—for example, the mean value, 50th percentile value, or 90th percentile value.

2. *What Constitutes a Significant Increase.* To determine whether an increase is considered to be significant, we propose to use a two part test. First, the increase must be statistically significant. We could use the student's "t" test, "F" test, or some other statistical test as appropriate, at a 95

percent confidence level for the statistical test. We specifically request comment on whether this type of statistical test is appropriate.

Second, if the cogenerated residue has statistically significant high levels of appendix VIII compounds, we propose that a second test be considered to determine whether the residue has been significantly affected—does the cogenerated residue pose a significantly increased health risk. We believe that consideration of health risk posed by these compounds is appropriate because Congress excluded residues from the subject devices based on their presumed high volume and low toxicity pending completion of the section 8002 studies. Thus, we believe that the test of applicability of the Bevill exclusion should consider whether the compounds present at statistically significant higher levels in the cogenerated residue are present at levels of concern from a conservative human health perspective. An alternative reading on the applicability of the Bevill amendment, on which we also request comment, would be to measure whether an increase is statistically significant without regard to the health-based significance of the increase (which could be viewed as a decision relating to whether the wastes warrant regulation, rather than whether they are properly withing the scope of the Bevill amendment).

We specifically request comment on whether it is appropriate to consider a health-based *de minimis* level of concern when determining applicability of the Bevill amendment in these cogeneration situations, and, if so, how such *de minimis* levels could be established. For example, the following approach could be used. For metals for which EP Toxicity (see § 261.24) levels have been established, those levels could be used as *de minimis* levels. Under this approach, the cogenerated residue would not be within the scope of the Bevill amendment if the levels of EP Toxic metals are significantly higher in the cogenerated residue than in the baseline residue and the cogenerated residue exhibited EP Toxicity.

For appendix VIII compounds other than the metals covered by EP Toxicity, we could use an alternative approach. This would include other metals (i.e., antimony, beryllium, nickel, and thallium), other inorganics that could reasonably be expected to be in the waste, and organic compounds that could reasonably be expected to be in the waste or that could result from

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[24] Specific residues subject to the Bevill exclusion (i.e., Mining Waste Exclusion) are listed in the April 17, 1989, Federal Register at 15316.

[25] In support of this reading, one court has held that residues from a secondary lead smelter are not covered by the Bevill amendment. Ilco Co. v. EPA (W.D. Ala. 1986).

[26] We note that the issue of the applicability of the Bevill amendment does not pertain to smelters processing indigenous waste. In such cases, the smelter is not coburning hazardous waste.

incomplete destruction during the burning or processing.[27]

For these compounds, we could apply the Toxicity Characteristic Leaching Procedure (TCLP) codified in appendix I, 40 CFR part 268 to obtain an extract or leachate from the residue.[28] We could then conservatively assume that an individual actually drinks the leachate as his sole source of drinking water over a lifetime to determine acceptable concentrations of toxic compounds. For noncarcinogenic compounds, we could establish *de minimis* levels based on the RfD. For carcinogenic compounds, we could establish *de minimis* levels as those that could not result in an incremental lifetime cancer risk greater than 10^{-5}.[29]

We also solicit comment on whether less conservative approaches should be adopted. Our concern is that any such approaches-for example, involving site-specific modeling—would not be self-implementing. The virtue of the approach outline above is easy implementability plus a clear way of showing whether the residue's character results from burning hazardous waste of Bevill materials.

C. Regulatory Impact of Today's Proposal

The foregoing discussion is not intended to change automatically at this time the regulatory status of residues from Bevill devices that burn or process hazardous waste. In most cases, EPA expects that these wastes' character is indeed determined by processing or burning the Bevill raw material. Thus, in the absence of data indicating otherwise, the policies regarding applicability of the Bevill amendment to cogenerated residues provided by the November 29, 1985, final rule and the May 6, 1987, proposed rule, as discussed above, remain in effect. EPA intends today's discussion to begin to gather the necessary data and to obatin comment on alternative approaches on which to base a more precise and workable test for determining whether a cogenerated

[27] See Midwest Research Institute, "Background Information Document for the Development of Regulations for PIC Emissions from Hazardous Waste Incinerators," December, 1988.

[28] We also request comment on whether, for organic compounds, the total concentration of the compound is the residue rather than the extract concentration should be used for the health-based test given that the purpose of burning toxic organic compounds in these devices should be to destroy the compounds.

[29] A draft compilation of health-based concentrations for use in determining applicability of the Bevill exclusion has been made for approximately 150 compounds based on EP Toxicity levels, maximum concentration levels, RfDs, and RSDs. See memorandum to the Docket from Dwight Hlustick, EPA, dated June 6, 1989.

residue remains within the scope of the Bevill amendment. Based on comment on today's discussion and additional Agency analysis, we hope to be in a position to develop a definitive test of Bevill applicability. Ideally, the Agency will establish a final rule on Bevill applicability when the boiler and industrial furnace standards are promulgated.

XI. Applicability of the Sham Recycling Policy

On March 16, 1983, EPA published an Enforcement Guidance (FR 11157) which provided guidance on burning low energy hazardous waste, ostensibly for energy recovery, in boilers and industrial furnaces. This guidance has been referred to as EPA's Sham Recycling Policy. This policy stated that when hazardous waste having a heating value less than 5,000 Btu/lb is burned in boilers or industrial furnaces, EPA generally considers the practice to be burning for destruction (i.e., incineration) rather than exempt burning for energy recovery. The proposed rules for boilers and industrial furnaces burning hazardous waste would apply to those devices irrespective of the purpose of burning. Thus, the proposed rules would supersede the sham recycling policy. A question has been raised regarding the status of the sham recycling policy in the interim between the time the rules are ultimately promulgated and a facility is issued a Part B permit.

The Agency is considering three options in this case. The first option is to rescind the sham recycling policy on the effective date of the final boiler/furnace regulations. As a result, industrial furnaces and boilers could begin burning low heating value hazardous waste at that time. The second alternative is to rescind the sham recycling policy when a facility comes into compliance with the interim status emission standards. In this case, the facility could commence burning low heating value hazardous waste during interim status once it complies with the emissions standards.

The last alternative is to have the sham recycling policy remain in effect until a Part B permit is issued. The Part B permit would address final emission and other standards, and the facility would have completed any trial burn or other emission testing requirements in conjunction with permit writer oversight.

EPA specifically requests comments on these alternatives for rescinding the sham recycling policy.

Regardless of which alternative EPA selects, the sham recycling policy would

not apply during the trial burn required to receive a Part B permit or during test burns conducted specifically in preparation for the trial burn. This exclusion is needed to ensure that the facility has the opportunity to conduct a successful trial burn using the wastes for which it wishes to be permitted. The permitting authority will have final approval of the waste types, waste quantities, and facility operating conditions when low heating value (less than 5,000 BTU/lb) wastes are burned in preparation for, and during, the trial burn.

XII. Regulation of Direct Transfer of Hazardous Waste from a Transport Vehicle to a Boiler or Industrial Furnace

Some permitting authorities have expressed concern about the practice of feeding hazardous waste fuels directly from transport vehicles (e.g., 6,000 gallon tankers) to industrial furnaces such as cement kilns. Although these operations may be exempt under § 261.6(c)(2) from the storage standards provided by parts 264 and 265, some permit authorities are concerned about: (1) The potential for fires, explosions, and spills during transfer operations; and (2) the potential for waste fuel flow interruptions and stratification of waste in the transport container which, in turn, could affect the ability of the burner to consistently provide efficient combustion of the waste. Approaches to address these issues are discussed below.

In situations where permit writers believe that such transfer operations pose a substantial risk of fires, explosions, or spills that is not adequately addressed by applicable regulatory controls, the permit writer should use the omnibus authority under section 3005(c)(3) of RCRA codified at § 270.32(b)(2) to provide additional permit conditions as may be necessary to protect human health and the environment.

With respect to the concern about fuel flow interruptions and waste stratification and the resultant effects on combustion efficiency, we request comment on whether blending and surge storage tanks should be required at all facilities burning hazardous waste. This is common practice at the vast majority of facilities. In fact, it could be argued that the primary reason that the practice of direct transfer from the transport vehicle to the burner is used at some cement kiln facilities in lieu of using a fixed blending/storage tank is to avoid the need to obtain a permit for the storage tank. (Hazardous waste fuel storage operations not "in existence" on May 29, 1986, and thus, not eligible for

interim status, must obtain a part 264, part B permit before they can operate.)

XIII. Updated Health Effects Data

In the 1987 proposal, appendices A & B presented reference air concentrations for noncarcinogens and unit risk values for carcinogens for those compounds in appendix VIII, part 261 for which the Agency had sufficient health effects data to establish such values. Since May 1987, several values have been revised based on new health effects data or evaluations. For the convenience of the reader, we are providing those entire appendices, incorporating the revised values, in today's notice as appendices I and J.

Dated: October 13, 1989.

William K. Reilly,

Administrator.

Appendix A: Background Support for PIC Controls

Hazard Posed by Emissions of Products of Incomplete Combustion (PICs)

The burning of hazardous waste containing toxic organic compounds listed in appendix VIII of 40 CFR part 261 under poor combustion conditions can result in substantial emissions of compounds that result from the incomplete combustion of constituents in the waste, as well as emissions of the original compounds which were not burned. The quantity of toxic organic compounds emitted depends on the concentration of the compounds in the waste, and the combustion conditions under which the waste is burned.

Data on typical PIC emissions from hazardous waste combustion sources were compiled and assessed in recent EPA studies.[30, 31] These studies identified 37 individual compounds in the stack gas of the eight full-scale hazardous waste incinerators tested, out of which 17 were volatile compounds and 20 semivolatile compounds. Eight volatile compounds (benzene, toluene, chloroform, trichloroethylene, carbon tetrachloride, tetrachloroethylene, chlorobenzene, and methylene chloride), and one semivolatile compound (naphthalene) were identified most frequently in over 50 percent of the tests.

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[30] Wallace, D. et al., "Products of Incomplete Combustion from Hazardous Waste Combustion," Draft Final Report. EPA Contract No. 68–03–3241, Acurex Corporation, Subcontractor No. ES 59689A, Work Assignment 5. Midwest Research Institute Project No. 8371–L(1), Kansas City, MO, June 1986.

[31] Trenholm, A., and C.C. Lee, "Analysis of PIC and Total Mass Emissions from an Incinerator," Proceedings of the Twelfth Annual Research Symposium on Land Disposal, Remedial Action, Incineration, and Treatment of Hazardous Waste, Cincinnati, OH, April 21–23, 1986, EPA/600–9–86/022, pp. 376–381, August 1986.

It was found that PIC emission rates vary widely from site-to-site which may be due, in part, to variations in waste feed composition and facility size. The median values of the nine compounds mentioned above range from 0.27 to 5.0 mg/min. Using a representative emission rate of 1 mg/min, the stack gas concentration of PICs in a medium-sized facility (250 m³/min combustion gas flow rate) would be 4 μg/m3 (0.004 μg/l).

The health risk posed by PIC emissions depends on the quantity and toxicity of the individual toxic components of the emissions, and the ambient levels to which persons are exposed. Estimates of risk to public health resulting from PICs, based on available emissions data, indicate that PIC emissions do not pose significant risks when incinerators are operated under optimum conditions. However, limited information about PICs is available. PIC emissions are composed of thousands of different compounds, some of which are in very minute quantities and cannot be detected and quantified without very elaborate and expensive sampling and analytical (S&A) techniques. Such elaborate S&A work is not feasible in trial burns for permitting purposes and can only be done in research tests. In addition, reliable S&A procedures simply do not exist for some types of PICs (e.g., water-soluble compounds). The most comprehensive analysis of PIC emissions from a hazardous waste incinerator identified and quantified only approximately 70 percent of organic emissions. Typical research-oriented field tests identify a much lower fraction—from 1–60 percent. Even if all the organic compounds emitted could be quantified, there are inadequate health effects data available to assess the resultant health risk. EPA believes that, due to the above limitations, additional testing will not, in the foreseeable future, be able to prove quantitatively whether PICs do or do not pose unacceptable health risk. Considering the uncertainties about PIC emissions and their potential risk to public health, it is therefore prudent to require that boilers and industrial furnaces operate at a high combustion efficiency to minimize PIC emissions. Given that carbon monoxide (CO) is the best available indicator of combustion efficiency, and a conservative indicator of combustion upset, we are proposing to limit the flue gas CO levels to levels that ensure PIC emissions are not likely to pose unacceptable health risk. In cases where CO concentrations exceed the proposed *de minimis* limit, higher

CO levels would be allowed under two alternative approaches: (1) If total hydrocarbon (THC) concentrations in the stack gas do not exceed a good operating practice-based limit of 20 ppmv; or (2) if the applicant demonstrates that THC emissions are not likely to pose unacceptable health risk using conservative, prescribed risk assessment procedures. Although we prefer the technology-based approach for reasons discussed in the text, we are requesting comment on the health-based alternative as well.

Use of CO Limits to Ensure Good Combustion Conditions

By definition, low CO flue gas levels are indicative of a boiler or industrial furnace (or any combustion device) operating at high combustion efficiency. Operating at high combustion efficiency helps ensure minimum emissions of unburned (or incompletely burned) organics.[32] In a simplified view of combustion of hazardous waste, the first stage is immediate thermal decomposition of the POHCs in the flame to form other, usually smaller, compounds, also referred to as PICs. These PICs are generally rapidly decomposed to form CO.

The second stage of combustion involves the oxidation of CO to CO_2 (carbon dioxide). The CO to CO_2 step is the slowest (rate controlling) step in the combustion process because CO is considered to be more thermally stable (difficult to oxidize) than other intermediate products of combustion of hazardous waste constituents. Since fuel is being fired continuously, both combustion stages are occurring simultaneously.

Using this view of waste combustion, CO flue gas levels cannot be correlated to DRE for POHCs and may not correlate well with PIC destruction. As discussed below, test data shown no correlation between CO and DRE, but do show a slight apparent correlation between CO and chlorinated PICs, and a fair correlation between CO and total unburned hydrocarbons. Low CO is an indicator of the status of the CO to CO_2 conversion process, the last, rate-limiting oxidation process. Since

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[32] Given that CO is a gross indicator of combustion performance, limiting CO may not absolutely minimize PIC emissions. This is because PICs can result from small pockets within the combustion zone where adequate time, temperature, and turbulence have not been provided to oxidize completely the combustion products of the POHCs. Available data, however, indicate that PIC emissions do not pose significant risk when combustion devices are operated at high combustion efficiency. EPA is conducting additional field and pilot scale testing to address this issue.

oxidation of CO to CO_2 occurs after destruction of the POHC and its (other) intermediates (PICs), the absence of CO is a useful indication of POHC and PIC destruction. The presence of high levels of CO in the flue gas is a useful indication of inefficient combustion and, at some level of elevated CO flue gas concentration, an indication of failure of the PIC and POHC destruction process. We believe it is necessary to limit CO levels to levels indicative of high combustion efficiency because we do not know the precise CO level that is indicative of significant failure of the PIC and POHC destruction process. It is possible that the critical CO level may be dependent on site-specific and event-specific factors (e.g., fuel type, air-to-fuel ratios, rate and extent of change of these and other factors that affect combustion efficiency). We believe limiting CO levels is prudent because: (1) It is a widely practiced approach to improving and monitoring combustion efficiency; and (2) most well designed and operated boilers and industrial furnaces can easily be operated in conformance with the proposed Tier I CO limit of 100 ppmv.

The Tier I CO limit of 100 ppmv would be specified in the permit even when (though) the CO levels during the trial burn were lower. EPA considered this issue carefully and the proposal is based on three considerations. First, permitting a CO level of 100 ppmv will not cause destruction and removal efficiencies to be less than the required 99.99 percent. Second, many combustion devices run very efficiently during a trial burn and achieve CO emissions under 10 ppmv. It may be difficult to achieve that high degree of efficiency on a consistent basis and specifying such low trial burn CO values may result in numerous unnecessary hazardous waste feed cut-offs due to CO exceedances. Third, the emission of PICs from incinerators has not been shown to increase linearly at such low CO levels. In fact, the trial burn data indicate that total organic emissions are consistently low (i.e., at levels that pose acceptable health risk) when CO emission levels are less than 100 ppmv. Two studies show that no measurable change in DRE is likely to occur for CO levels up to 100 ppmv. The first study generated data from combustion of a 12 component mixture in a bench scale facility.[33] The CO

$$Combustion\ Efficiency\ (CE) = \frac{percent\ CO_2}{percent\ CO_2 + percent\ CO}\ (100)$$

levels ranged from 15 to 522 ppm without a significant correlation to the destruction efficiency for the compounds investigated. The second study was conducted on a pilot scale combustor.[34] Test runs were conducted with average CO concentrations ranging from 30 to 700 ppmv. When the concentration was less than 220 ppmv, no apparent decrease in DRE was noticed, but higher CO concentrations showed a definite decrease in DRE. EPA specifically invites comments on whether the permit should limit CO according to actual trial burn values in lieu of the limits specified here.

Supporting Information on CO as a Surrogate for PICs

Substantial information is available that indicate CO emissions may relate to PIC emissions.

Combustion efficiency is directly related to CO by the following equation:

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[33] Hall D.L. et al, "Thermal Decomposition Properties of a Twelve Component Organic Mixture", Hazardous Wastes & Hazardous Materials, Vol. 3, No. 4 pp 441–449, 1986.

[34] Waterland, L.R. "Pilot-scale Investigation of Surrogate Means of Determining POHC Destruction" Final Report for the Chemical Manufacturers' Association, ACUREX Corporation, Mountain View, California, July 1983.

CE has been used as a measure of completeness of combustion.[35] EPA's regulations for incineration of waste PCBs at 40 CFR 761.70 require that combustion efficiency be maintained above 99.9 percent. As combustion becomes less efficient or less complete, at some point, the emission of total organics will increase and smoke will eventually result. It is probable that some quantity of toxic organic compounds will be present in these organic emissions. Thus, CE or CO levels provide an indication of the potential for total organic emissions and possibly toxic PICs. Data are not available, however, to correlate these variables quantitatively with PICs in combustion processes.

Several studies have been conducted to evaluate CO monitoring as a method to measure the performance of hazardous waste combustion. Though correlations with destruction efficiency of POHCs have not been found, the data from these studies generally show that as combustion conditions deteriorate, both CO and total hydrocarbon emissions increase. These data support the relation between CO and increased organic emissions discussed above. In one of these studies,[36] an attempt was made to correlate the concentrations of CO with the concentrations of four common PICs (benzene, toluene, carbon tetrachloride, and trichloroethylene) in stack gases of full scale incinerators. For a plot of CO versus benzene, one of the most common PICs, there is considerable scatter in the data indicating that parameters other than CO affect the benzene levels. However, there is a trend in the data that suggests that when benzene levels are high, CO levels also are high. The converse has not been found to be true; when benzene levels are low, CO levels are not always low. Similar trends were observed for toluene and carbon tetrachloride, but not for trichloroethylene. In the pilot-scale study by Waterland cited earlier, similar trends were observed for

chlorobenzene and methylene chloride and in another study [37] similar trends were observed for total chlorinated PICs. These data support the conclusion that when the emission rates of some commonly identified PICs are sufficiently high, it is likely that CO emissions will also be higher than typical levels.

More importantly, however, available data indicate that when CO emissions are low (e.g., under 100 ppmv), PIC emissions are always low (i.e., at levels that pose acceptable health risk). The converse may not be true: when CO is high, PIC levels may or may not be high. Thus, the Agency believes that CO is a conservative indicator of potential PIC emissions and, given that CO monitoring is already required in the present regulations, the emission levels should be limited to low levels indicative of high combustion efficiency. (For those facilities where CO emissions may be high but PIC emissions low, we are providing an opportunity under Tier II of the proposed rule to demonstrate that, in fact, PIC emissions pose acceptable health risks at elevated CO levels.)

Appendix B: Emission Screening Limits for Total Hydrocarbons (mg/s)

Terrain adjusted effective stack height (meters)	Noncomplex terrain		Complex terrain
	Urban land use	Rural land use	
4	5.4E+01	2.8E+01	1.3E+01
6	6.1E+01	3.2E+01	1.9E+01
8	6.9E+01	3.6E+01	2.7E+01
10	7.7E+01	4.2E+01	4.0E+01
12	8.8E+01	5.1E+01	4.9E+01
14	9.9E+01	6.2E+01	6.0E+01
16	1.1E+02	7.7E+01	6.9E+01
18	1.3E+02	8.6E+01	7.7E+01
20	1.4E+02	1.2E+02	8.5E+01
22	1.6E+02	1.5E+02	9.4E+01
24	1.8E+02	1.9E+02	1.0E+02
26	2.0E+02	2.5E+02	1.2E+02
28	2.3E+02	3.1E+02	1.3E+02
30	2.6E+02	4.0E+02	1.4E+02
35	3.4E+02	6.3E+02	1.8E+02
40	4.3E+02	9.6E+02	2.2E+02
45	5.4E+02	1.3E+03	2.7E+02
50	7.0E+02	1.8E+03	3.3E+02
55	8.8E+02	2.3E+03	4.1E+02
60	1.1E+03	3.1E+03	5.0E+02
65	1.3E+03	4.1E+03	6.2E+02
70	1.5E+03	4.9E+03	6.9E+02
75	1.7E+03	5.8E+03	7.7E+02

Terrain adjusted effective stack height (meters)	Noncomplex terrain		Complex terrain
	Urban land use	Rural land use	
80	1.9E+03	6.9E+03	8.6E+02
85	2.2E+03	8.2E+03	9.7E+02
90	2.5E+03	9.7E+03	1.1E+03
95	2.8E+03	1.2E+04	1.2E+03
100	3.2E+03	1.4E+04	1.4E+03
105	3.6E+03	1.6E+04	1.5E+03
110	4.1E+03	2.0E+04	1.7E+03
115	4.6E+03	2.3E+04	1.9E+03
120	5.3E+03	2.8E+04	2.1E+03

Appendix C: Performance Specifications for Continuous Emission Monitoring of Carbon Monoxide and Oxygen in Hazardous Waste Incinerators, Boilers, and Industrial Furnaces

1.0 Applicability and Principle

1.1 *Applicability.* This specification is to be used for evaluating the acceptability of carbon monoxide (CO) and oxygen (02) continuous emission monitoring systems (CEMS) installed on hazardous waste incinerators, boilers, and industrial furnaces.

This specification is intended to be used in evaluating the acceptability of the CEMS at the time of or soon after installation and at other times as specified in the regulations. This specification is not designed to evaluate the CEMS performance over an extended period of time nor does it identify specific routine calibration techniques and other auxiliary procedures to assess CEMS performance. The source owner or operator, however, is responsible to calibrate, maintain, and operate the CEMS.

1.2 *Principle.* Installation and measurement location specifications, performance and equipment specifications, test procedures, and data reduction procedures are included in this specification. Relative accuracy (RA) tests, calibration error (Ec) tests, calibration drift (CD) tests, and response time (RT) tests are conducted to determine conformance of the CEMS with the specification.

2.0 Definitions

2.1 *Continuous Emission Monitoring System (CEMS).* The CEMS comprises all the equipment used to generate data and includes the sample extraction and

[35] We specifically request comments on whether combustion efficiency, as defined above in the text (i.e., considering both CO and CO₂ emissions) should be used to control PIC emissions rather than CO alone.

[36] Trenholm, A., P. Gorman, and G. Jungclaus, "Performance Evaluation of Full-Scale Hazardous Waste Incinerators, Vol. 2—Incinerator Performance Results." EPA-600/2-84-181b, NTIS No. PB 85-129518, November 1984.

[37] Chang, D. P. et al., "Evaluation of a Pilot-Scale Circulating Bed Combustor as a Potential Hazardous Waste Incinerator," APCA Journal, Vol. 37, No. 3, pp. 266-274, March 1987.

transport hardware, the analyzer(s), and the data recording/processing hardware (and software).

2.2 *Continuous.* A continuous monitor is one in which the sample to be analyzed passes the measurement section of the analyzer without interruption, and, which evaluates the detector response to the sample at least once each 15 seconds and which computes and records the results at least every 60 seconds.

2.2.1 *Hourly Rolling Average.* An hourly rolling average is the arithmetic mean of the 60 most recent 1-minute average values recorded by the continuous monitoring system.

2.3 *Monitoring System Types.* There are three basic types of monitoring systems: extractive, cross-stack, and in-situ. Carbon monoxide monitoring generally are extractive or cross-stack, while oxygen monitors are either extractive or in-situ.

2.3.1 *Extractive.* Extractive systems use a pump or other mechanical, pneumatic, or hydraulic means to draw a small portion of the stack or flue gas and convey it to the remotely located analyzer.

2.3.2 *In-situ.* In-situ analyzers place the sensing or detecting element directly in the flue gas stream and thus perform the analysis without removing a sample from the stack.

2.3.3 *Cross-stack.* Cross-stack analyzers measure the parameter of interest by placing a source beam on one side of the stack and either the detector (in single-pass instruments) or a retro-reflector (in double-pass instruments) on the other side and measuring the parameter of interest (e.g., CO) by the attenuation of the beam by the gas in its path.

2.4 *Span.* The upper limit of the gas concentration measurement range.

2.5 *Instrument Range.* The maximum and minimum concentration that can be measured by a specific instrument. The minimum is often stated or assumed to be zero and the range expressed only as the maximum. If a single analyzer is used, for measuring multiple ranges, (either manually or automatically), the performance standards expressed as a percentage of full scale apply to all ranges.

2.6 *Calibration Drift.* Calibration drift is the change in the response or output of an instrument from a reference value over time. Drift is measured by comparing the responses to a reference standard over time with no adjustment of instrument settings.

2.7 *Response Time.* The response time of a system or part of a system is the amount of time between a step change in the system input (e.g. change

of calibration gas) until the data recorder displays 95 percent of the final value.

2.8 *Accuracy.* Accuracy is a measure of agreement between a measured value and an accepted or true value and is usually expressed as the percentage difference between the true and measured values relative to the true value. For this performance specification, the accuracy is checked by conducting a calibration error (Ec) test and a relative accuracy (RA) test.

2.8.1 *Calibration Error.* Calibration error is a measure of the deviation of a measured value at the analyzer mid range from a reference value.

2.8.2 *Relative Accuracy.* Relative accuracy is the comparison of the CEMS response to a value measured by a reference test method (RM). The applicable reference test methods are Method 10 (Determination of Carbon Monoxide from Stationary Sources) and Method 3 (Gas Analysis for Carbon Monoxide, Oxygen Excess Air, and Dry Molecular Weight). These methods are found in 40 CFR part 60, appendix A.

3.0 Installation and Measurement Location Specifications

3.1 *CEMS Measurement Location.* The best or optimum location of the sample interface for the monitoring system is determined by a number of factors, including ease of access for calibration and maintenance, the degree to which sample conditioning will be required, the degree to which it represents total emissions, and the degree to which it represents the combustion situation in the firebox. The location should be as free from in-leakage influences as possible and reasonably free from severe flow disturbances. The sample location should be at least two equivalent duct diameters downstream from the nearest control device, point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate occurs and at least 0.5 diameters upstream from the exhaust or control device. The equivalent duct diameter is calculated as per 40 CFR part 60, appendix A, method 1, section 2.1.

The sample path of sample point(s) should include the concentric inner 50 percent of the stack or duct cross section. For circular ducts, this is 0.707 × diameter and a single-point probe, therefore, should be located between 0.141 × diameter and 0.839 × diameter from the stack wall and a multiple-point probe should have sample inlets in this region. A location which meets both the diameter and the cross-section criteria will be acceptable.

If these criteria are not achievable of if the location is otherwise less than optimum, the possibility of stratification should be investigated. To check for stratification, the oxygen concentration should also be measured as verification of oxygen in-leakage. For rectangular ducts, at least nine sample points located at the center of similarly shaped, equal area division of the cross section should be used. For circular ducts, 12 sample points (i.e., six points on each of the two perpendicular diameter) should be used, locating the points as described in 40 CFR part 60, appendix A, method 1. Calculate the mean value for all sample points and select the point(s) or path that provides a value equivalent to the mean. For these purposes, if no single value is more than 15 percent different from the mean and if no two single values are different from each other by more than 20 percent of the mean, then the gas can be assumed homogeneous and can be sampled anywhere. The point(s) or path should be within the inner 50 percent of the area.

Both the oxygen and CO monitors should be installed at the same location or very close to each other. If this is not possible, they may be installed at different locations if the effluent gases at both sample locations are not stratified and there is no in-leakage of air between sampling locations.

3.2 *Reference Method (RM) Measurement Location and Traverse Points.* Select, as appropriate, an accessible RM measurement point at least two equivalent diameters downstream from the nearest control device, the point of pollutant generation, or other point at which a change in the pollutant concentration or emission rate may occur, and at least a half equivalent diameter upstream from the effluent exhaust or control device. When pollutant concentration changes are due solely to oxygen in-leakage (e.g., air heater leakages) and pollutants and diluents are simultaneously measured at the same location, a half diameter may be used in lieu of two equivalent diameters. The CEMS and RM locations need not be the same. Then select traverse points that assure acquisition of representative samples over the stack or duct cross section. The minimum requirements are as follows: Establish a "measurement line" that passes through the centroidal area and in the direction of any expected stratification. If this line interferes with the CEM measurements, displace the line up to 30 cm (or 5 percent of the equivalent diameter of the cross section, whichever is less) from the centroidal area. Locate three traverse points at 16.7, 50.0, and 83.3

percent of the measurement line. If the measurement line is longer than 2.4 m and pollutant stratification is not expected, the tester may choose to locate the three tranverse points on the line at 0.4, 1.2, and 2.0 m from the stack or duct wall. This option must not be used at points where two streams with different pollutant concentrations are combined. The tester may select other traverse points, provided that they can be shown to the satisfaction of the Administrator to provide a representative sample over the stack or duct cross section. Conduct all necessary RM tests within 3 cm (but not less than 3 cm from the stack or duct wall) of the traverse points.

4.0 Monitoring System Performance Specifications

Table C–1 summarizes the performance standards for the continuous monitoring systems. Each of the items is discussed in the following paragraphs. Two sets of standards for CO are given—one for low range measurement and another for high range measurement since the proposed CO limits are dual range. The high range standards relate to measurement and quantification of short duration high concentration peaks, while the low range standards relate to the overall average operating condition of the incinerator. The dual-range specification can be met either by using two separate analyzers, one for each range, or by using dual range units which have the capability of meeting both standards with a single unit. In the latter case, when the reading goes above the full scale measurement value of the lower range, the higher range operation will be started automatically.

TABLE C–1.—PERFORMANCE SPECIFICATIONS OF CO AND OXYGEN MONITORS

Parameter	CO monitors		Oxygen monitors
	Low range	High range	
Calibration drift 24 h.	<5% FS [1]	<5% FS	<0.5% O2.
Calibration error [2].	<5% FS	<5% FS	<0.5% O2.
Response time.	<1.5 min	<1.5 min	<1.5 min.
Relative accuracy.	<The greater of 10% of RM or 20ppm.		<The greater of 20% of RM or 1.0% O2.

[1] FS means full scale measurement range.
[2] Expressed as the sum of the mean absolute value plus the 95% confidence interval of a series of measurements.

4.1 *CEMS Span Values.* The span values shown below in Table C–2 are to

be established for the continuous emission monitoring systems.

TABLE C–2.—CEMS SPAN VALUES FOR CO AND OXYGEN MONITORS

	CO monitors		Oxygen monitors (%)
	Low range (ppm)	High range (ppm)	
Tier 1 rolling average format.	200	3,000	25
Tier 1 alternate format.	200	3,000	25
Tier 2 rolling average format.	2×permit limit.	3,000	25
Tier 2 alternate format.	2×permit limit.	1.1×permitted peak value.	25

4.2 *System Measurement Range.* In order to measure both the high and low concentrations consistently with the same or similar degree of accuracy, system measurement range maximum span specifications are given for both the low and high range monitors. The system measurement range chosen is based upon the permitted level and the span value presented in section 4.1.

The owner or operator must choose a measurement range that includes zero and a high-level value. The high-level value is chosen by the source owner and operator as follows:

1. For the low range CO measurement, the high level value is set between 1.5 times the permit limit and the span value specified in section 4.1.

2. For the high range CO measurements, except for Tier 2, alternate format, the high level value is set between 2000 ppm as a minimum and the span value specified in section 4.1.

3. For the high range CO measurement under Tier 2 using the alternate format, the high level value is set at the span value specified in section 4.1.

4. For oxygen, the high level value is set between 1.5 times the highest level measured during the trial burn and the span value specified in section 4.1.

The calibration gas, or gas cell values used to establish the data recorder scale should produce the zero and high level values.

4.3 *Response Time.* The mean response time for the CO monitor(s) should not exceed 1.5 minutes to achieve 95 percent of the final stable value. For the oxygen monitor, the mean response time should not exceed 15 min to achieve 95 percent of the final stable value.

4.4 *Calibration Drift.* The CEMS calibration must not drift or deviate from the reference value of the gas

cylinder or gas cell by more than 5 percent full scale in 24 hr for the CO low range and the CO high range. For oxygen the calibration drift must be less than 0.5 percent O_2 in 24 hr. The calibration drift specification must not be exceeded for six out of the seven test days required during the test (see Section 5 for the test procedures).

4.5 *Calibration Error.* The calibration error specification evaluates the system accuracy at the midpoint of the measurement range by the calibration error test described in Section 6. The test determines the difference between the measured value and the expected value at this midpoint.

The calibration error of the CEMS must not exceed 5 percent full scale for CO. The calibration error of the oxygen CEMS must not exceed 0.5 percent O_2.

4.6 *Relative Accuracy.* The relative accuracy (RA) of the carbon monoxide CEMS must not exceed 10 percent of the mean value of the reference method (RM) test data or 20 ppm CO, whichever is greater. Note that during the relative accuracy test, the CO level may exceed the full scale of the low range monitor. When this occurs, the mean CEMS measurement value should be calculated using the appropriate data from both the low range and high range monitors.

The relative accuracy of the oxygen CEMS must not exceed 20 percent of the mean value of the RM test data or 1 percent oxygen, whichever is greater.

5.0 Performance Specification Test Period

5.1 *Pretest Preparation.* Install the CEMS, prepare the RM test site according to the specifications in Section 3, and prepare the CEMS for operation according to the manufacturer's written instructions.

5.2 *Calibration Drift Test Period.* Prior to initiating the calibration drift tests conduct the calibration error test and the response time test according to the test procedures established in Section 6. The carbon monoxide and oxygen (if applicable) monitoring systems must be evaluated separately.

5.3 *Calibration Drift Test Period.* The monitoring system should be operated for some time before attempting drift checks because most systems need a period of equilibration and adjustment before the performance is reasonably stable. At least one week (168 hr) of continuous operation is recommended before attempting drift tests.

While the facility is operating at normal conditions, determine the magnitude of the calibration drift (CD) once each day (at 24-hr intervals) for

seven consecutive days according to the procedure given in section 6. The carbon monoxide and oxygen (if applicable) monitoring systems must be evaluated separately.

5.4 *RA Test Period.* Conduct the RA test according to the procedure given in section 6 while the facility is operating at normal conditions. The RA test may be conducted during the CD test period. The RA test may be conducted separately for each of the monitors (carbon monoxide and oxygen, if applicable) or may be conducted as a combined test so that the results are calculated only for the corrected CO concentration (i.e., CO corrected to 7 percent oxygen); the latter approach is preferred.

6.0 Performance Specification Test Procedures.

6.1 *Response Time.* The response time tests apply to all types of monitors, but will generally have significance only for extractive systems. The entire system is checked with this procedure including sample extraction and transport (if applicable), sample conditioning (if applicable), gas analyses, and the data recording.

Introduce zero gas into the system. For extractive systems, the calibration gases should be introduced at the probe as near to the sample location as possible. For in-situ systems, introduce the zero gas at the sample interface so that all components active in the analysis are tested. When the system output has stabilized (no change greater than 1 percent of full scale for 30 s), switch to monitor stack effluent and wait for a stable value. Record the time (upscale response time) required to reach 95 percent of the final stable value. Next, introduce a high level calibration gas and repeat the above procedure (stable, switch to sample, stable, record). Repeat the entire procedure three times and determine the mean upscale and downscale response times. The slower or longer of the two means is the system response time.

6.2 *Calibration Error Test*

6.2.1 *Procedure.* The procedure for testing calibration error is to set the instrument zero and span with the appropriate standards and then repeatedly measure a standard in the middle of the range. In order to minimize bias from previous analyses, the sequence of standard introduction should alternate between high and low standards prior to the mid-level standard (e.g., high, mid, low, mid, high, mid, low, mid, etc.) until six analyses of the mid-level standard are obtained, with three values obtained from upscale

approach and three values obtained from downscale approach.

The differences between the measured instrument output and the expected output of the reference standards are used as the data points.

62.2 *Calculations.* Summarize the results on a data sheet. For each of the six measurements made, calculate the arithmetic difference between the midpoint reference value and the measured value. Then calculate the mean of the difference, standard deviation, confidence coefficient, and calibration error using Equations 2–1, 2–2, 2–3, and 2–4 presented in Section 7.

6.3 *Zero and Span Calibration Drift.* The purpose of the calibration drift (CD) checks is to determine the ability of the CEMS to maintain its calibration over a specified period of time. The performance specifications establish a standard related to span drift. Each drift test is conducted seven times and the system(s) are allowed to exceed the limit once during the test.

During the drift tests, no adjustment of the system is permitted except those automatic internal adjustments which are part of the automatic compensation circuits integral to the analyzer. If periodic automatic adjustments are made to the CEMS zero and calibration settings, conduct the daily CD test immediately before these adjustments, or conduct it in such a way that the CD can be determined (calculated). Subsequent CEMS operation must include the same system configuration as used during the performance testing.

Select a reference gas with a CO or O_2 concentration between 80 and 100 percent of the full-scale measurement range of the analyzer; ambient air (20.9 percent O_2) may be used as the reference gas for oxygen. The zero gas should contain the lowest concentration recommended by the manufacturer. Prior to the test, calibrate the instrument. At the beginning of the test, introduce the selected zero and span reference gases (or cells or filters). After 24 hr and at 24-hr intervals thereafter, alternately introduce both the zero and span reference gases, wait until a stable reading is obtained and record the values reported by the system. Subtract the recorded CEMS response from the reference value. Repeat this procedure for 7 days, obtaining eight values of zero and span gas measurements (the initial values and seven 24-hr readings). The difference between the established or reference value for the span and the measured value may not exceed the specifications in Table 4.1 more than once, and the average value must not exceed the specification.

6.4 *Relative Accuracy Test Procedure*

6.4.1 *Sampling Strategy for RM Test.* Conduct the RM tests in such a way that they will yield results representative of the emissions from the source and can be correlated to the CEMS data. Although it is preferable to conduct the oxygen, moisture (if needed), and CO measures simultaneously, the diluent and moisture measurements that are taken within a 30- to 60-min period which includes the pollutant measurements, may be used to calculate dry pollutant concentration corrected to 7 percent O_2. For each run, make a sample traverse of at least 21 min, sampling for 7 min per point.

6.4.2 *Correlation of RM and CEMS Data.* Correlate the CEMS and the RM test data as to the time and duration by first determining from the CEMS final output (the one used for reporting) the integrated average pollutant concentration during each pollutant RM test period. Consider system response time, if important, and confirm that the pair of results are on a consistent moisture, temperature, and diluent concentration basis. Then, compare each integrated CEMS value against the corresponding average RM value. Make a direct comparison of the RM results and CEMS integrated average value. When oxygen monitoring is required by the regulation to calculate carbon monoxide normalized to 7 percent O_2, the RM test results should be calculated and compared on this basis. This is, the CO concentrations normalized to 7 percent O_2 measured by the CEMS.

6.4.3 *Number of RM Tests.* Conduct a minimum of nine sets of all necessary RM tests. The tester may choose to perform more than nine sets of RM tests. If this option is chosen, the tester may, at his discretion, reject a maximum of three sets of the test results so long as the total number of test results used to determine the RA is greater than or equal to nine, but they must report all data including the rejected data.

6.4.4 *Calculations.* Summarize the results on a data sheet. Calculate the mean of the RM values. Calculate the arithmetic differences between the RM and the CEMS output sets. Then calculate the mean of the difference, standard deviation, confidence coefficient, and CEMS RA, using Equations 2–1, 2–2, 2–3, and 2–5.

7.0 Equations

7.1 *Arithmetic Mean.* Calculate the arithmetic mean of the difference, d, of a data set as follows:

$$d_{av.} = \frac{1}{n} \times \sum_{i=1}^{n} d_i \qquad \text{(Eq. 2-1)}$$

Where n = number of data points

$\sum\limits_{i=1}^{n} d_i$ = algebraic sum of the individual differences d_i

When the mean of the differences of pairs of data is calculated, be sure to correct the data for moisture, if applicable.

7.2 *Standard Deviation.* Calculate the standard deviation, Sd, as follows:

$$S_d = \left(\frac{\sum\limits_{i=1}^{n} d_i{}^2 - \dfrac{\left(\sum\limits_{i=1}^{n} d_i\right)^2}{n}}{n-1} \right)^{\frac{1}{2}} \qquad \text{(Eq. 2-2)}$$

7.3 *Confidence Coefficient.* Calculate the 2.5 percent error confidence coefficient (one-tailed), CC, as follows:

$$CC = t_{0.975} \times \frac{S_d}{\sqrt{n}} \qquad \text{(Eq. 2-3)}$$

Where $t_{0.975}$ = t-value

TABLE 7-1.—VALUES

n^a	$t_{0.975}$	n^a	$t_{0.975}$	n^a	$t_{0.975}$
2	12.706	7	2.447	12	2.201
3	4.303	8	2.365	13	2.179
4	3.182	9	2.306	14	2.160
5	2.776	10	2.262	15	2.145
6	2.571	11	2.228	16	2.131

[a] The values in this table are already corrected for n–1 degrees of freedom. Use n equal to the number of individual values.

7.4 *Calibration Error.* Calculate the calibration error (Ec) of a set of data as follows:

$$\text{For carbon monoxide: } E_c = \frac{|d_{av}| + |CC|}{FS} \times 100 \quad \text{(Eq. 2-4)}$$

For oxygen[38]: $E_c = |d_{av}| + |CC|$
where: $|d_{av}|$=absolute value of the mean of differences (from Equation 2–1)
$|CC|$=absolute value of the confidence coefficient (from Equation 2–3)
FS=full scale span of monitoring system (for calculation of CO calibration error only)

7.5 *Relative Accuracy.* Calculate the relative accuracy (RA) of a set of data as follows:

$$RA = \frac{|d_{av}| + |CC|}{RM} \times 100 \quad \text{(Eq. 2–5)}$$

where: $|d_{av}|$ =absolute value of the mean of differences (from Equation 2–1)
$|CC|$ =absolute value of the confidence coefficient (from Equation 2–3)
RM=average value indicated by the Reference Method.

8.0 Quality Assurance

It is the responsibility of the owner/operator to assure proper calibration, maintenance, and operation of the CEMS on a continual basis. The owner/operator should establish a QA program to evaluate and monitor CEMS performance on a continual basis. The following QA guidelines are presented:

1. Conduct a daily calibration check for each monitor. Adjust the calibration if the check indicates the instrument's calibration drift exceeds the

[38] For oxygen, the calibration error is expressed as % O_2 and the term $||d| + |C||$ is not divided by FS or multiplied by 100.

specification established in Paragraph 4.4.

2. Conduct a daily system audit. During the audit, review the calibration check data, inspect the recording system, inspect the control panel warning lights, and inspect the sample transport/interface system (e.g., flowmeters, filters), as appropriate.

3. Conduct a quarterly calibration error test at the span midpoint.

4. Repeat the entire performance specification test every second year.

9.0 Reporting

At a minimum (check with the appropriate regional office, or State, or local agency for additional requirements, if any), summarize in tabular form, the results of the response time tests, calibration error tests, calibration drift tests, and the relative accuracy tests. Include all data sheets, calculations, charts (records of CEMS responses), cylinder gas concentration certifications, and calibration cell response certifications (if applicable), necessary to substantiate that the performance of the CEMS met the performance specifications.

10.0 References

10.1. Jahnke, james A. and G. J. Aldina, "Handbook: Continuous Air Pollution Source Monitoring Systems," U.S. Environmental Protection Agency Technology Transfer, Cincinnati, Ohio 45268, EPA–625/6–79–005, June 1979.

10.2. "Gaseous Continuous Emission Monitoring Systems—Performance Specification Guidelines for SO_2, NO_x,

CO_2, O_2, and TRS." U.S. Environmental Protection Agency OAQPS/ESED, Research Triangle Park, North Carolina, 27711, EPA–450/3–82–026, October 1982.

10.3. "Quality Assurance Handbook for Air Pollution Measurement Systems: Volume I. Principles," U.S. Environmental Protection Agency ORD/EMSL, Research Triangle Park, North Carolina, 27711 EPA–600/9–76–006, December 1984.

10.4. Michie, Raymond, M. Jr. et al., "Performance Test Results and Comparative Data for Designated Reference Methods for Carbon Monoxide," U.S. Environmental Protection Agency ORD/EMSL, Research Triangle Park, North Carolina, 27711, EPA–600/S4–83–013, September 1982.

10.5. Ferguson, B.B., R.E. Lester and W. J. Mitchell, "Field Evaluation of Carbon Monoxide and Hydrogen Sulfide Continuous Emission Monitors at an Oil Refinery," U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711, EPA–600/4–82–054, August 1982.

Appendix D: Performance Specifications for Continuous Emissions Monitoring of Total Hydrocarbons in Hazardous Waste Incinerators, Boilers and Industrial Furnaces

Note: This proposed method may be revised to allow gas conditioning including cooling to between 40 °F and 64 °F and the use of condensate traps to reduce the moisture content of sample gas entering the FID to less than 2%. The gas conditioning system, however, should not allow the

sample gas to be bubbled through a water column as this would remove water-soluble organic compounds. Further, although heating the sampling line and FID may be advisable to reduce operation and maintenance problems, it may not be required in the final procedure. Comments on the gas conditioning system are encouraged.

1.0 Applicabiltiy and Principle

1.1 *Applicability.* This method applies to the measurement of total hydrocarbons as a surrogate measure for the total gaseous organic concentration of the combustion gas stream. The concentration is expressed in terms of propane.

1.2 *Principle.* A gas sample is extracted from the source through a heated sample line and heated glass fiber filter to a flame ionization detector (FID). Results are reported as volume concentration equivalents of the propane.

2.0 Definitions

2.1 *Measurement System.* The total equipment required for the determination of the gas concentration. The system consists of the following major subsystems:

2.1.1 *Sample Interface.* That portion of the system that is used for one or more of the following: sample acquisition, sample transportation, sample conditioning, or protection of the analyzer from the effects of the stack effluent.

2.1.2 *Organic Analyzer.* That portion of the system that senses organic concentration and generates an output proportional to the gas concentration.

2.1.3 *Data Recorder.* That portion of the system that records a permanent record of the measurement values.

2.2 *Span Value.* For most incinerators a 50 ppm propane span is appropriate. Higher span values may be necessary if propane emissions are significant. For convenience, the span value should correspond to 100 percent of the recorder scale.

2.3 *Calibration Gas.* A known concentration of a gas in an appropriate diluent gas.

2.4 *Zero Drift.* The difference in the measurement system response to a zero level calibration gas before and after a stated period of operation during which no unscheduled maintenance, repair, or adjustment took place.

2.5 *Calibration Drift.* The difference in the measurement system response to a mid-level calibration gas before and after a stated period of operation during which no unscheduled maintenance, repair or adjustment took place.

2.6 *Response Time.* The time interval from a step change in pollutant concentration at the inlet to the emission measurement system to the time at which 95 percent of the corresponding final value is reached as displayed on the recorder.

2.7 Calibration Error. The difference between the gas concentration indicated by the measurement system and the known concentration of the calibration gas.

3.0 Apparatus

An acceptable measurement system includes a sample interface system, a calibration valve, gas filter and a pump preceding the analyzer. THC measurement systems are designated HOT or COLD systems based on the operating temperatures of the system. In HOT systems, all components in contact with the sample gas (probe, calibration valve, filter, and sample lines) as well as all parts of the flame ionization analyzer between the sample inlet and the flame ionization detector (FID) must be maintained between 150–175 °C. This includes the sample pump if it is located on the inlet side of the FID. A condensate trap may be installed, if necessary, to prevent any condensate entering the FID.

The essential components of the measurement system are described below:

3.1 *Organic Concentration Analyzer.* A flame ionization detector (FID) capable of meeting or exceeding the specifications in this method.

3.2 *Sample Probe.* Stainless steel, or equivalent, three-hole rake type. Sample holes shall be 4 mm in diameter or smaller and located at 16.7, 50, and 83.3 percent of the equivalent stack diameter. Alternatively, a single opening prcbe may be used so that a gas sample is collected from the centrally located 10 percent area of the stack cross-section.

3.3 *Sample Line.* Stainless steel or Teflon [39] tubing to transport the sample gas to the analyzer. The sample line should be heated to between 150° and 175°C for a heated probe.

3.4 *Calibration Valve Assembly.* A heated three-way valve assembly to direct the zero and calibration gases to the analyzers is recommended. Other methods, such as quick-connect lines, to route calibration gas to the analyzers are applicable.

3.5 *Particulate Filter.* An in-stack or an out-of-stack glass fiber filter is recommended if exhaust gas particulate loading is significant. An out-of-stack filter must be heated.

3.6 *Recorder.* A strip-chart recorder, analog computer, or digital recorder for

recording measurement data. The minimum data recording requirement is one measurement value per minute.

Note: This method is often applied in highly explosive areas. Caution and care should be exercised in choice of equipment and installation.

4.0 Calibration and Other Gases

Gases used for calibration, fuel, and combustion air (if required) are contained in compressed gas cylinders. Preparation of calibration gases shall be done according to the procedure in Protocol No. 1, listed in reference 9.2. Additionally, the manufacturer of the cylinder should provide a recommended shelf life for each calibration gas cylinder over which the concentration does not change more than ±2 percent from the certified value.

4.1 *Fuel.* A 40 percent hydrogen and 60 percent helium or 40 percent hydrogen and 60 percent nitrogen gas mixture is recommended to avoid an oxygen synergism effect that reportedly occurs when oxygen concentration varies significantly from a mean value.

4.2 *Zero Gas.* High purity air with less than 0.1 parts per million by volume (ppm) of organic material methane or carbon equivalent or less than 0.1 percent of the span value, whichever is greater.

4.3 *Low-level Calibration Gas.* Propane calibration gas (in air or nitrogen) with a concentration equivalent to 20 to 30 percent of the applicable span value.

4.4 *Mid-level Calibration Gas.* Propane calibration gas (in air or nitrogen) with a concentration equivalent to 45 to 55 percent of the applicable span value.

4.5 *High-level Calibration Gas.* Propane calibration gas with a concentration equivalent to 80 to 90 percent of the applicable span value.

5.0 Measurement System Performance Specifications

5.1 *Zero Drift.* Less than ±3 percent of the span value.

5.2 *Calibration Drift.* Less than ±3 percent of the span value.

5.3 *Calibration Error.* Less than ±5 percent of the calibration gas value.

6.0 Pretest Preparations

6.1 *Selection of Sampling Site.* The location of the sampling site is generally specified by the applicable regulation or purpose of the test, i.e., exhaust stack, inlet line, etc. The sample port shall be located at least 1.5 meters or 2 equivalent diameters upstream of the gas discharge to the atmosphere.

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[39] Mention of trade names or specific products does not constitute endorsement by the Environmental Protection Agency.

6.2 *Location of Sample Probe*. Install the sample probe so that the probe is centrally located in the stack, pipe, or duct and is sealed tightly at the stack port connection.

6.3 *Measurement System Preparation*. Prior to the emission test, assemble the measurement system following the manufacturer's written instructions in preparing the sample interface and the organic analyzer. Make the system operable.

6.4 *Calibration Error Test*. Immediately prior to the test series, (within 2 hours of the start of the test) introduce zero gas and high-level calibration gas at the calibration valve assembly. Adjust the analyzer output to the appropriate levels, if necessary. Calculate the predicted response for the low-level and mid-level gases based on a linear response line between the zero and high-level responses. Then introduce low-level and mid-level calibration gases successively to the measurement system. Record the analyzer responses for low-level and mid-level calibration gases and determine the differences between the measurement system responses and the predicted responses. These differences must be less than 5 percent of the respective calibration gas value. If not, the measurement system is not acceptable and must be replaced or repaired prior to testing. No adjustments to the measurement system shall be conducted after the calibration and before the drift check (Section 7.3). If adjustments are necessary before the completion of the test series, perform the drift checks prior to the required adjustments and repeat the calibration following the adjustments. If multiple electronic ranges are to be used, each additional range must be checked with a mid-level calibration gas to verify the multiplication factor.

6.5 *Response Time Test*. Introduce zero gas into the measurement system at the calibration valve assembly. When the system output has stabilized, switch quickly to the high-level calibration gas. Record the time from the concentration change to the measurement system response equivalent to 95 percent of the

step change. Repeat the test three times and average the results.

7.0 *Emission Measurement Test Procedure*

7.1 *Organic Measurement*. Begin sampling at the start of the test period, recording time and any required process information as appropriate. In particular, note on the recording chart periods of process interruption or cyclic operation.

7.2 *Drift Determination*. Immediately following the completion of the test period and hourly during the test period, reintroduce the zero and mid-level calibration gases, one at a time, to the measurement system at the calibration valve assembly. (Make no adjustments to the measurement system until after both the zero and calibration drift checks are made.) Record the analyzer response. If the drift values exceed the specified limits, invalidate the test results preceding the check and repeat the test following corrections to the measurement system. Alternatively, recalibrate the test measurement system as in Section 6.4 and report the results using both sets of calibration data (i.e., data determined prior to the test period and data determined following the test period).

8.0 *Organic Concentration Calculations*

Determine the average organic concentration in terms of ppmv propane. The average shall be determined by the integration of the output recording over the period specified in the applicable regulation.

9.0 *Quality Assurance*

It is the responsibility of the owner/operator to assure proper calibration, maintenance, and operation of the CEMS on a continual basis. The owner/operator should establish a QA program to evaluate and monitor performance on a continual basis. The following checks should routinely be done.

1. Conduct a daily calibration check for each monitor. Adjust the calibration if the check indicates the instrument's calibration drift exceeds the specification established in paragraph 5.0.

2. Conduct a daily system audit. During the audit, review the calibration check data, inspect the recording system, inspect the control panel warning lights, and inspect the sample transport/interface system (e.g., flowmeters, filters), as appropriate.

3. Conduct a quarterly calibration error test at the span midpoint.

4. Repeat the entire performance specification test every second year.

10.0 *Reporting of Total Hydrocarbon Levels*

THC levels from the trial burn will be reported as ppm propane. Under the health-based alternative approach to assess THC emissions, the THC levels would need to be converted to mg/s. This conversion is accomplished with the following equation:

THC, mg/s = (THC ppm propane) × (Stack gas Flow) × 2.8×10^{-2}

Where:
- THC ppm propane is the total hydrocarbon concentration as actually measured by this method in ppm of propane,
- Stack gas flow is in dry standard cubic meters per minute measured by EPA Reference Method 5 (or Modified EPA Method 5) during the DRE trial burn, and
- 2.8×10^{-2} is a constant to account for the conversion of units, differences in FID response to various compounds and weighted average molecular weights.

11.0 *References*

11.1 Measurement of Volatile Organic Compounds—Guideline Series. U.S. Environmental Protection Agency. Research Triangle Park, N. C. Publication No. EPA–450/2–78–041. June 1978. p. 46–54.

11.2 Traceability Protocol for Establishing True Concentrations of Gases Used for Calibration and Audits of Continuous Source Emission Monitors (Protocol No. 1). U.S. Environmental Protection Agency, Environmental Monitoring and Support Laboratory. Research Triangle Park, N. C. June 1978.

11.3 Gasoline Vapor Emission Laboratory Evaluation—Part 2. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. Research Triangle Park, N. C. EMB Report No. 75–GAS–6. August 1975.

Appendix E: Feed Rate and Emission Rate Screening Limits for Metals and HCL

TABLE E–1.—FEED RATE SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for urban areas					
	Antimony (lb/hr)	Barium (lb/hr)	Lead (lb/hr)	Mercury (lb/hr)	Silver (lb/hr)	Thallium (lb/hr)
4m	1.3E−01	2.2E+01	4.0E−02	1.3E−01	1.3E+00	1.3E−01
6m	1.5E−01	2.5E+01	4.5E−02	1.5E−01	1.5E+00	1.5E−01
8m	1.7E−01	2.8E+01	5.1E−02	1.7E−01	1.7E+00	1.7E−01
10m	1.9E−01	3.2E+01	5.8E−01	1.9E−01	1.9E+00	1.9E−01

TABLE E-1.—FEED RATE SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN—Continued

Terrain-adjusted effective stack height	Values for urban areas					
	Antimony (lb/hr)	Barium (lb/hr)	Lead (lb/hr)	Mercury (lb/hr)	Silver (lb/hr)	Thallium (lb/hr)
12m	2.2E−01	3.6E+01	6.5E−02	2.2E−01	2.2E+00	2.2E−01
14m	2.4E−01	4.1E+01	7.3E−02	2.4E−01	2.4E+00	2.4E−01
16m	2.8E−01	4.6E+01	8.3E−02	2.8E−01	2.8E+00	2.8E−01
18m	3.1E−01	5.2E+01	9.4E−02	3.1E−01	3.1E+00	3.1E−01
20m	3.5E−01	5.9E+01	1.1E−01	3.5E−01	3.5E+00	3.5E−01
22m	4.0E−01	6.6E+01	1.2E−01	4.0E−01	4.0E+00	4.0E−01
24m	4.5E−01	7.5E+01	1.4E−01	4.5E−01	4.5E+00	4.5E−01
26m	5.1E−01	8.5E+01	1.5E−01	5.1E−01	5.1E+00	5.1E−01
28m	5.7E−01	9.6E+01	1.7E−01	5.7E−01	5.7E+00	5.7E−01
30m	6.5E−01	1.1E+02	1.9E−01	6.5E−01	6.5E+00	6.5E−01
35m	8.3E−01	1.4E+02	2.5E−01	8.3E−01	8.3E+00	8.3E−01
40m	1.1E+00	1.8E+02	3.2E−01	1.1E+00	1.1E+01	1.1E+00
45m	1.4E+00	2.3E+02	4.1E−01	1.3E+00	1.4E+01	1.4E+00
50m	1.7E+00	2.9E+02	5.2E−01	1.7E+00	1.7E+01	1.7E+00
55m	2.2E+00	3.6E+02	6.5E−01	2.2E+00	2.2E+01	2.2E+00
60m	2.7E+00	4.5E+02	8.0E−01	2.7E+00	2.7E+01	2.7E+00
65m	3.3E+00	5.5E+02	9.9E−01	3.3E+00	3.3E+01	3.3E+00
70m	3.7E+00	6.2E+02	1.1E+00	3.7E+00	3.7E+01	3.7E+00
75m	4.2E+00	7.0E+02	1.3E+00	4.2E+00	4.2E+01	4.2E+00
80m	4.8E+00	8.0E+02	1.4E+00	4.8E+00	4.8E+01	4.8E+00
85m	5.4E+00	9.1E+02	1.6E+00	5.4E+00	5.4E+01	5.4E+00
90m	6.2E+00	1.0E+03	1.9E+00	6.2E+00	6.2E+01	6.2E+00
95m	7.0E+00	1.2E+03	2.1E+00	7.0E+00	7.0E+01	7.0E+00
100m	8.0E+00	1.3E+03	2.4E+00	7.9E+00	8.0E+01	8.0E+00
105m	9.0E+00	1.5E+03	2.7E+00	9.0E+00	9.0E+01	9.0E+00
110m	1.0E+01	1.7E+03	3.1E+00	1.0E+01	1.0E+02	1.0E+01
115m	1.2E+01	1.9E+03	3.5E+00	1.2E+01	1.2E+02	1.2E+01
120m	1.3E+01	2.2E+03	4.0E+00	1.3E+01	1.3E+02	1.3E+01

TABLE E-1.—FEED RATE SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for rural areas					
	Antimony (lb/hr)	Barium (lb/hr)	Lead (lb/hr)	Mercury (lb/hr)	Silver (lb/hr)	Thallium (lb/hr)
4m	6.9E−02	1.1E+01	2.1E−02	6.9E−02	6.9E−01	6.9E−02
6m	7.9E−02	1.3E+01	2.4E−02	7.9E−02	7.9E−01	7.9E−02
8m	9.0E−02	1.5E+01	2.7E−02	9.0E−02	9.0E−01	9.0E−02
10m	1.0E−01	1.7E+01	3.1E−02	1.0E−01	1.0E+00	1.0E−01
12m	1.3E−01	2.1E+01	3.8E−02	1.3E−01	1.3E+00	1.3E−01
14m	1.5E−01	2.6E+01	4.6E−02	1.5E−01	1.5E+00	1.5E−01
16m	1.9E−01	3.2E+01	5.7E−02	1.9E−01	1.9E+00	1.9E−01
18m	2.4E−01	4.0E+01	7.1E−02	2.4E−01	2.4E+00	2.4E−01
20m	2.9E−01	4.9E+01	8.8E−02	2.9E−01	2.9E+00	2.9E−01
22m	3.8E−01	6.3E+01	1.1E−01	3.7E−01	3.8E+00	3.8E−01
24m	4.8E−01	8.0E+01	1.4E−01	4.8E−01	4.8E+00	4.8E−01
26m	6.1E−01	1.0E+02	1.8E−01	6.1E−01	6.1E+00	6.1E−01
28m	7.7E−01	1.3E+02	2.3E−01	7.7E−01	7.7E+00	7.7E−01
30m	9.8E−01	1.6E+02	2.9E−01	9.8E−01	9.8E+00	9.8E−01
35m	1.6E+00	2.6E+02	4.7E−01	1.6E+00	1.6E+01	1.6E+00
40m	2.4E+00	4.0E+02	7.1E−01	2.4E+00	2.4E+01	2.4E+00
45m	3.3E+00	5.5E+02	9.9E−01	3.3E+00	3.3E+01	3.3E+00
50m	4.4E+00	7.3E+02	1.3E+00	4.4E+00	4.4E+01	4.4E+00
55m	5.8E+00	9.6E+02	1.7E+00	5.8E+00	5.8E+01	5.8E+00
60m	7.6E+00	1.3E+03	2.3E+00	7.6E+00	7.6E+01	7.6E+00
65m	1.0E+01	1.7E+03	3.0E+00	1.0E+01	1.0E+02	1.0E+01
70m	1.2E+01	2.0E+03	3.6E+00	1.2E+01	1.2E+02	1.2E+01
75m	1.4E+01	2.4E+03	4.3E+00	1.4E+01	1.4E+02	1.4E+01
80m	1.7E+01	2.8E+03	5.1E+00	1.7E+01	1.7E+02	1.7E+01
85m	2.0E+01	3.4E+03	6.1E+00	2.0E+01	2.0E+02	2.0E+01
90m	2.4E+01	4.0E+03	7.2E+00	2.4E+01	2.4E+02	2.4E+01
95m	2.9E+01	4.8E+03	8.6E+00	2.9E+01	2.9E+02	2.9E+01
100m	3.4E+01	5.7E+03	1.0E+01	3.4E+01	3.4E+02	3.4E+01
105m	4.1E+01	6.8E+03	1.2E+01	4.1E+01	4.1E+02	4.1E+01
110m	4.8E+01	8.1E+03	1.5E+01	4.8E+01	4.8E+02	4.8E+01
115m	5.8E+01	9.6E+03	1.7E+01	5.8E+01	5.8E+02	5.8E+01
120m	6.9E+01	1.1E+04	2.1E+01	6.9E+01	6.9E+02	6.9E+01

TABLE E–2.—FEED RATE SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN COMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for use in urban and rural areas					
	Antimony (lb/hr)	Barium (lb/hr)	Lead (lb/hr)	Mercury (lb/hr)	Silver (lb/hr)	Thallium (lb/hr)
4m	3.1E−02	5.2E+00	9.4E−03	3.1E−02	3.1E−01	3.1E−02
6m	4.6E−02	7.7E+00	1.4E−02	4.6E−02	4.6E−01	4.6E−02
8m	6.7E−02	1.1E+01	2.0E−02	6.7E−02	6.7E−01	6.7E−02
10m	9.9E−02	1.7E+01	3.0E−02	9.9E−02	9.9E−01	9.9E−02
12m	1.2E−01	2.0E+01	3.6E−02	1.2E−01	1.2E+00	1.2E−01
14m	1.5E−01	2.5E+01	4.4E−02	1.5E−01	1.5E+00	1.5E−01
16m	1.7E−01	2.9E+01	5.2E−02	1.7E−01	1.7E+00	1.7E−01
18m	1.9E−01	3.2E+01	5.7E−02	1.9E−01	1.9E+00	1.9E−01
20m	2.1E−01	3.5E+01	6.3E−02	2.1E−01	2.1E+00	2.1E−01
22m	2.3E−01	3.9E+01	7.0E−02	2.3E−01	2.3E+00	2.3E−01
24m	2.6E−01	4.3E+01	7.7E−02	2.6E−01	2.6E+00	2.6E−01
26m	2.9E−01	4.8E+01	8.6E−02	2.9E−01	2.9E+00	2.9E−01
28m	3.2E−01	5.3E+01	9.5E−02	3.2E−01	3.2E+00	3.2E−01
30m	3.5E−01	5.8E+01	1.0E−01	3.5E−01	3.5E+00	3.5E−01
35m	4.4E−01	7.3E+01	1.3E−01	4.3E−01	4.4E+00	4.4E−01
40m	5.4E−01	8.9E+01	1.6E−01	5.4E−01	5.4E+00	5.4E−01
45m	6.6E−01	1.1E+02	2.0E−01	6.6E−01	6.6E+00	6.6E−01
50m	8.1E−01	1.4E+02	2.4E−01	8.1E−01	8.1E+00	8.1E−01
55m	1.0E+00	1.7E+02	3.0E−01	1.0E−00	1.0E+01	1.0E−00
60m	1.2E+00	2.1E+02	3.7E−01	1.2E+00	1.2E+01	1.2E+00
65m	1.5E+00	2.5E+02	4.6E−01	1.5E+00	1.5E+01	1.5E+00
70m	1.7E+00	2.8E+02	5.1E−01	1.7E+00	1.7E+01	1.7E+00
75m	1.9E+00	3.2E+02	5.7E−01	1.9E+00	1.9E+01	1.9E+00
80m	2.1E+00	3.6E+02	6.4E−01	2.1E+00	2.1E+01	2.1E+00
85m	2.4E+00	4.0E+02	7.2E−01	2.4E+00	2.4E+01	2.4E+00
90m	2.7E+00	4.5E+02	8.0E−01	2.7E+00	2.7E+01	2.7E+00
95m	3.0E+00	5.0E+02	9.0E−01	3.0E+00	3.0E+01	3.0E+00
100m	3.4E+00	5.6E+02	1.0E+00	3.4E+00	3.4E+01	3.4E+00
105m	3.8E+00	6.3E+02	1.1E+00	3.8E+00	3.8E+01	3.8E+00
110m	4.2E+00	7.0E+02	1.3E+00	4.2E+00	4.2E+01	4.2E+00
115m	4.7E+00	7.9E+02	1.4E+00	4.7E+00	4.7E+01	4.7E+00
120m	5.3E+00	8.8E+02	1.6E+00	5.3E+00	5.3E+01	5.3E+00

TABLE E–3. FEED RATE SCREENING LIMITS FOR CARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for use in urban areas				Values for use in rural areas			
	Arsenic (lb/hr)	Cadmium (lb/hr)	Chromium (lb/hr)	Beryllium (lb/hr)	Arsenic (lb/hr)	Cadmium (lb/hr)	Chromium (lb/hr)	Beryllium (lb/hr)
4m	1.0E−03	2.5E−03	3.7E−04	1.9E−03	5.3E−04	1.3E−03	1.9E−04	9.5E−04
6m	1.2E−03	2.8E−03	4.2E−04	2.1E−03	6.1E−04	1.5E−03	2.2E−04	1.1E−03
8m	1.3E−03	3.2E−03	4.7E−04	2.4E−03	7.0E−04	1.7E−03	2.5E−04	1.3E−03
10m	1.5E−03	3.6E−03	5.3E−04	2.7E−03	8.0E−04	1.9E−03	2.9E−04	1.4E−03
12m	1.7E−03	4.0E−03	6.0E−04	3.0E−03	9.8E−04	2.3E−03	3.5E−04	1.8E−03
14m	1.9E−03	4.5E−03	6.8E−04	3.4E−03	1.2E−03	2.9E−03	4.3E−04	2.1E−03
16m	2.1E−03	5.1E−03	7.7E−04	3.8E−03	1.5E−03	3.5E−03	5.3E−04	2.6E−03
18m	2.4E−03	5.8E−03	8.7E−04	4.3E−03	1.8E−03	4.4E−03	6.6E−04	3.3E−03
20m	2.7E−03	6.5E−03	9.8E−04	4.9E−03	2.3E−03	5.5E−03	8.2E−04	4.1E−03
22m	3.1E−03	7.4E−03	1.1E−03	5.5E−03	2.9E−03	6.9E−03	1.0E−03	5.2E−03
24m	3.5E−03	8.3E−03	1.3E−03	6.3E−03	3.7E−03	8.8E−03	1.3E−03	6.6E−03
26m	3.9E−03	9.4E−03	1.4E−03	7.1E−03	4.7E−03	1.1E−02	1.7E−03	8.4E−03
28m	4.5E−03	1.1E−02	1.6E−03	8.0E−03	6.0E−03	1.4E−02	2.1E−03	1.1E−02
30m	5.0E−03	1.2E−02	1.8E−03	9.0E−03	7.6E−03	1.8E−02	2.7E−03	1.4E−02
35m	6.5E−03	1.5E−02	2.3E−03	1.2E−02	1.2E−02	2.9E−02	4.3E−03	2.2E−02
40m	8.2E−03	2.0E−02	2.9E−03	1.5E−02	1.8E−02	4.4E−02	6.6E−03	3.3E−02
45m	1.0E−02	2.5E−02	3.8E−03	1.9E−02	2.6E−02	6.1E−02	9.2E−03	4.6E−02
50m	1.3E−02	3.2E−02	4.8E−03	2.4E−02	3.4E−02	8.1E−02	1.2E−02	6.1E−02
55m	1.7E−02	4.0E−02	6.1E−03	3.0E−02	4.5E−02	1.1E−01	1.6E−02	8.0E−02
60m	2.1E−02	5.0E−02	7.4E−03	3.7E−02	5.9E−02	1.4E−01	2.1E−02	1.1E−01
65m	2.5E−02	6.1E−02	9.1E−03	4.6E−02	7.8E−02	1.9E−01	2.8E−02	1.4E−01
70m	2.9E−02	6.9E−02	1.0E−02	5.2E−02	9.3E−02	2.2E−01	3.3E−02	1.7E−01
75m	3.3E−02	7.8E−02	1.2E−02	5.9E−02	1.1E−01	2.6E−01	4.0E−02	2.0E−01
80m	3.7E−02	8.9E−02	1.3E−02	6.7E−02	1.3E−01	3.1E−01	4.7E−02	2.4E−01
85m	4.2E−02	1.0E−01	1.5E−02	7.6E−02	1.6E−01	3.7E−01	5.6E−02	2.8E−01
90m	4.8E−02	1.1E−01	1.7E−02	8.6E−02	1.9E−01	4.5E−01	6.7E−02	3.3E−01
95m	5.4E−02	1.3E−01	1.9E−02	9.7E−02	2.2E−01	5.3E−01	8.0E−02	4.0E−01
100m	6.2E−02	1.5E−01	2.2E−02	1.1E−01	2.6E−01	6.3E−01	9.5E−02	4.7E−01
105m	7.0E−02	1.7E−01	2.5E−02	1.3E−01	3.2E−01	7.5E−01	1.1E−01	5.6E−01
110m	7.9E−02	1.9E−01	2.8E−02	1.4E−01	3.7E−01	9.0E−01	1.3E−01	6.7E−01
115m	9.0E−02	2.2E−01	3.2E−02	1.6E−01	4.5E−01	1.1E+00	1.6E−01	8.0E−01
120m	1.0E−01	2.4E−01	3.7E−02	1.8E−01	5.3E−01	1.3E+00	1.9E−01	9.5E−01

TABLE E-4.—FEED RATE SCREENING LIMITS FOR CARCINOGENIC METALS FOR FACILITIES IN COMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for urban and rural areas			
	Arsenic (lb/hr)	Cadmium (lb/hr)	Chromium (lb/hr)	Beryllium (lb/hr)
4m	2.4E-04	5.8E-04	8.7E-05	4.4E-04
6m	3.6E-04	8.5E-04	1.3E-04	6.4E-04
8m	5.2E-04	1.2E-03	1.9E-04	9.4E-04
10m	7.7E-04	1.8E-03	2.8E-04	1.4E-03
12m	9.4E-04	2.2E-03	3.4E-04	1.7E-03
14m	1.1E-03	2.7E-03	4.1E-04	2.1E-03
16m	1.3E-03	3.2E-03	4.8E-04	2.4E-03
18m	1.5E-03	3.5E-03	5.3E-04	2.6E-03
20m	1.6E-03	3.9E-03	5.9E-04	2.9E-03
22m	1.8E-03	4.3E-03	6.5E-04	3.2E-03
24m	2.0E-03	4.6E-03	7.2E-04	3.6E-03
26m	2.2E-03	5.3E-03	7.9E-04	4.0E-03
28m	2.5E-03	5.9E-03	8.8E-04	4.4E-03
30m	2.7E-03	6.5E-03	9.7E-04	4.9E-03
35m	3.4E-03	8.1E-03	1.2E-03	6.0E-03
40m	4.2E-03	9.9E-03	1.5E-03	7.4E-03
45m	5.1E-03	1.2E-02	1.8E-03	9.2E-03
50m	6.3E-03	1.5E-02	2.3E-03	1.1E-02
55m	7.8E-03	1.9E-02	2.8E-03	1.4E-02
60m	9.6E-03	2.3E-02	3.4E-03	1.7E-02
65m	1.2E-02	2.8E-02	4.2E-03	2.1E-02
70m	1.3E-02	3.2E-02	4.7E-03	2.4E-02
75m	1.5E-02	3.5E-02	5.3E-03	2.7E-02
80m	1.7E-02	4.0E-02	5.9E-03	3.0E-02
85m	1.9E-02	4.4E-02	6.7E-03	3.3E-02
90m	2.1E-02	5.0E-02	7.4E-03	3.7E-02
95m	2.3E-02	5.6E-02	8.3E-03	4.2E-02
100m	2.6E-02	6.2E-02	9.3E-03	4.7E-02
105m	2.9E-02	7.0E-02	1.0E-02	5.2E-02
110m	3.3E-02	7.8E-02	1.2E-02	5.9E-02
115m	3.7E-02	8.7E-02	1.3E-02	6.5E-02
120m	4.1E-02	9.8E-02	1.5E-02	7.3E-02

TABLE E-5.—EMISSIONS SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for urban areas					
	Antimony (g/sec)	Barium (g/sec)	Lead (g/sec)	Mercury (g/sec)	Silver (g/sec)	Thallium (g/sec)
4m	1.7E-02	2.8E+00	5.1E-03	1.7E-02	1.7E-01	1.7E-02
6m	1.9E-02	3.2E+00	5.7E-03	1.9E-02	1.9E-01	1.9E-02
8m	2.1E-02	3.6E+00	6.4E-03	2.1E-02	2.1E-01	2.1E-02
10m	2.4E-02	4.0E+00	7.3E-03	2.4E-02	2.4E-01	2.4E-02
12m	2.7E-02	4.6E+00	8.2E-03	2.7E-02	2.7E-01	2.7E-02
14m	3.1E-02	5.1E+00	9.3E-03	3.1E-02	3.1E-01	3.1E-02
16m	3.5E-02	5.8E+00	1.0E-02	3.5E-02	3.5E-01	3.5E-02
18m	3.9E-02	6.6E+00	1.2E-02	3.9E-02	3.9E-01	3.9E-02
20m	4.4E-02	7.4E+00	1.3E-02	4.4E-02	4.4E-01	4.4E-02
22m	5.0E-02	8.4E+00	1.5E-02	5.0E-02	5.0E-01	5.0E-02
24m	5.7E-02	9.5E+00	1.7E-02	5.7E-02	5.7E-01	5.7E-02
26m	6.4E-02	1.1E+01	1.9E-02	6.4E-02	6.4E-01	6.4E-02
28m	7.2E-02	1.2E+01	2.2E-02	7.2E-02	7.2E-01	7.2E-02
30m	8.2E-02	1.4E+01	2.5E-02	8.2E-02	8.2E-01	8.2E-02
35m	1.1E-01	1.8E+01	3.2E-02	1.1E-01	1.1E+00	1.1E-01
40m	1.3E-01	2.2E+01	4.0E-02	1.3E-01	1.3E+00	1.3E-01
45m	1.7E-01	2.8E+01	5.1E-02	1.7E-01	1.7E+00	1.7E-01
50m	2.2E-01	3.6E+01	6.5E-02	2.2E-01	2.2E+00	2.2E-01
55m	2.7E-01	4.6E+01	8.2E-02	2.7E-01	2.7E+00	2.7E-01
60m	3.4E-01	5.6E+01	1.0E-01	3.4E-01	3.4E+00	3.4E-01
65m	4.1E-01	6.9E+01	1.2E-01	4.1E-01	4.1E+00	4.1E-01
70m	4.7E-01	7.8E+01	1.4E-01	4.7E-01	4.7E+00	4.7E-01
75m	5.3E-01	8.9E+01	1.6E-01	5.3E-01	5.3E+00	5.3E-01
80m	6.0E-01	1.0E+02	1.8E-01	6.0E-01	6.0E+00	6.0E-01
85m	6.9E-01	1.1E+02	2.1E-01	6.9E-01	6.9E+00	6.9E-01
90m	7.8E-01	1.3E+02	2.3E-01	7.8E-01	7.8E+00	7.8E-01
95m	8.8E-01	1.5E+02	2.7E-01	8.8E-01	8.8E+00	8.8E-01
100m	1.0E+00	1.7E+02	3.0E-01	1.0E+00	1.0E+01	1.0E+00
105m	1.1E+00	1.9E+02	3.4E-01	1.1E+00	1.1E+01	1.1E+00
110m	1.3E+00	2.2E+02	3.9E-01	1.3E+00	1.3E+01	1.3E+00
115m	1.5E+00	2.4E+02	4.4E-01	1.5E+00	1.5E+01	1.5E+00
120m	1.7E+00	2.8E+02	5.0E-01	1.7E+00	1.7E+01	1.7E+00

TABLE E-5 (CONTINUED).–EMISSIONS SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for rural areas					
	Antimony (g/sec)	Barium (g/sec)	Lead (g/sec)	Mercury (g/sec)	Silver (g/sec)	Thallium (g/sec)
4m	8.7E−03	1.4E+00	2.6E−03	8.7E−03	8.7E−02	8.7E−03
6m	9.9E−03	1.7E+00	3.0E−03	9.9E−03	9.9E−02	9.9E−03
8m	1.1E−02	1.9E+00	3.4E−03	1.1E−02	1.1E−01	1.1E−02
10m	1.3E−02	2.2E+00	3.9E−03	1.3E−02	1.3E−01	1.3E−02
12m	1.6E−02	2.7E+00	4.8E−03	1.6E−02	1.6E−01	1.6E−02
14m	1.9E−02	3.2E+00	5.8E−03	1.9E−02	1.9E−01	1.9E−02
16m	2.4E−02	4.0E+00	7.2E−03	2.4E−02	2.4E−01	2.4E−02
18m	3.0E−02	5.0E+00	9.0E−03	3.0E−02	3.0E−01	3.0E−02
20m	3.7E−02	6.2E+00	1.1E−02	3.7E−02	3.7E−01	3.7E−02
22m	4.7E−02	7.9E+00	1.4E−02	4.7E−02	4.7E−01	4.7E−02
24m	6.0E−02	1.0E+01	1.8E−02	6.0E−02	6.0E−01	6.0E−02
26m	7.7E−02	1.3E+01	2.3E−02	7.7E−02	7.7E−01	7.7E−02
28m	9.7E−02	1.6E+01	2.9E−02	9.7E−02	9.7E−01	9.7E−02
30m	1.2E−01	2.1E+01	3.7E−02	1.2E−01	1.2E+00	1.2E−01
35m	2.0E−01	3.3E+01	5.9E−02	2.0E−01	2.0E+00	2.0E−01
40m	3.0E−01	5.0E+01	9.0E−02	3.0E−01	3.0E+00	3.0E−01
45m	4.2E−01	7.0E+01	1.3E−01	4.2E−01	4.2E+00	4.2E−01
50m	5.5E−01	9.2E+01	1.7E−01	5.5E−01	5.5E+00	5.5E−01
55m	7.3E−01	1.2E+02	2.2E−01	7.3E−01	7.3E+00	7.3E−01
60m	9.6E−01	1.6E+02	2.9E−01	9.6E−01	9.6E+00	9.6E−01
65m	1.3E+00	2.1E+02	3.8E−01	1.3E+00	1.3E+01	1.3E+00
70m	1.5E+00	2.5E+02	4.5E−01	1.5E+00	1.5E+01	1.5E+00
75m	1.8E+00	3.0E+02	5.4E−01	1.8E+00	1.8E+01	1.8E+00
80m	2.1E+00	3.6E+02	6.4E−01	2.1E+00	2.1E+01	2.1E+00
85m	2.6E+00	4.3E+02	7.7E−01	2.6E+00	2.6E+01	2.6E+00
90m	3.0E+00	5.1E+02	9.1E−01	3.0E+00	3.0E+01	3.0E+00
95m	3.6E+00	6.0E+02	1.1E+00	3.6E+00	3.6E+01	3.6E+00
100m	4.3E+00	7.2E+02	1.3E+00	4.3E+00	4.3E+01	4.3E+00
105m	5.1E+00	8.5E+02	1.5E+00	5.1E+00	5.1E+01	5.1E+00
110m	6.1E+00	1.0E+03	1.8E+00	6.1E+00	6.1E+01	6.1E+00
115m	7.3E+00	1.2E+03	2.2E+00	7.3E+00	7.3E+01	7.3E+00
120m	8.6E+00	1.4E+03	2.6E+00	8.6E+00	8.6E+01	8.6E+00

TABLE E-6.—EMISSIONS SCREENING LIMITS FOR NONCARCINOGENIC METALS FOR FACILITIES IN COMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for use in urban and rural areas					
	Antimony (g/sec)	Barium (g/sec)	Lead (g/sec)	Mercury (g/sec)	Silver (g/sec)	Thallium (g/sec)
4m	3.9E−03	6.6E−01	1.2E−03	3.9E−02	3.9E−02	3.9E−03
6m	5.8E−03	9.7E−01	1.7E−03	5.8E−03	5.8E−02	5.8E−03
8m	8.5E−03	1.4E+00	2.6E−03	8.5E−03	8.5E−02	8.5E−03
10m	1.2E−02	2.1E+00	3.7E−03	1.2E−02	1.2E−01	1.2E−02
12m	1.5E−02	2.5E+00	4.6E−03	1.5E−01	1.5E−01	1.5E−02
14m	1.9E−02	3.1E+00	5.6E−03	1.9E−02	1.9E−01	1.9E−02
16m	2.2E−02	3.6E+00	6.5E−03	2.2E−02	2.2E−01	2.2E−02
18m	2.4E−02	4.0E+00	7.2E−03	2.4E−02	2.4E−01	2.4E−02
20m	2.7E−02	4.4E+00	8.0E−03	2.7E−02	2.7E−01	2.7E−02
22m	2.9E−02	4.9E+00	8.8E−03	2.9E−02	2.9E−01	2.9E−02
24m	3.3E−02	5.4E+00	9.8E−03	3.3E−02	3.3E−01	3.3E−02
26m	3.6E−02	6.6E+00	1.2E−02	3.6E−02	3.6E−01	4.0E−02
28m	4.0E−02	6.6E+00	1.2E−02	4.0E−02	4.0E−01	4.0E−02
30m	4.4E−02	7.4E+00	1.3E−02	4.4E−02	4.4E−01	4.4E−02
35m	5.5E−02	9.1E+00	1.6E−02	5.5E−02	5.5E−01	5.5E−02
40m	6.8E−02	1.1E+01	2.0E−02	6.8E−02	6.6E−01	6.8E−02
45m	8.3E−02	1.4E+01	2.5E−02	8.3E−02	8.3E−01	8.3E−02
50m	1.0E−01	1.7E+01	3.1E−02	1.0E−01	1.0E+00	1.0E−01
55m	1.3E−01	2.1E+01	3.8E−02	1.3E−01	1.3E+00	1.3E−01
60m	1.6E−01	2.6E+01	4.7E−02	1.6E−01	1.6E+00	1.6E−01
65m	1.9E−01	3.2E+01	5.8E−02	1.9E−01	1.9E+00	1.9E−01
70m	2.2E−01	3.6E+01	6.5E−02	2.2E−01	2.2E+00	2.2E−01
75m	2.4E−01	4.0E+01	7.2E−02	2.4E−01	2.4E+00	2.4E−01
80m	2.7E−01	4.5E+01	8.1E−02	2.7E−01	2.7E+00	2.7E−01
85m	3.0E−01	5.0E+01	9.1E−02	3.0E−01	3.0E+00	3.0E−01
90m	3.4E−01	5.6E+01	1.0E−01	3.4E−01	3.4E+00	3.4E−01
95m	3.8E−01	6.3E+01	1.1E−01	3.8E−01	3.8E+00	3.8E−01
100m	4.2E−01	7.1E+01	1.3E−01	4.2E−01	4.2E+00	4.2E−01
105m	4.7E−01	7.9E+01	1.4E−01	4.7E−01	4.7E+00	4.7E−01
110m	5.3E−01	8.9E+01	1.6E−01	5.3E−01	5.3E+00	5.3E−01
115m	5.9E−01	9.9E+01	1.8E−01	5.9E−01	5.9E+00	5.9E−01
120m	6.7E−01	1.1E−02	2.0E−01	6.7E−01	6.7E+00	6.7E−01

TABLE E-7.—EMISSIONS SCREENING LIMITS FOR CARCINOGENIC METALS FOR FACILITIES IN NONCOMPLEX TERRAIN

Terrain-adjusted effective stack height	Values for use in urban areas				Values for use in rural areas			
	Arsenic (g/sec)	Cadmium (g/sec)	Chromium (g/sec)	Beryllium (g/sec)	Arsenic (g/sec)	Cadmium (g/sec)	Chromium (g/sec)	Beryllium (g/sec)
4m	1.3E-04	3.1E-04	4.7E-05	2.3E-04	6.7E-05	1.6E-04	2.4E-05	1.2E-04
6m	1.5E-04	3.5E-04	5.3E-05	2.6E-04	7.7E-05	1.8E-04	2.8E-05	1.4E-04
8m	1.7E-04	4.0E-04	6.0E-05	3.0E-04	8.8E-05	2.1E-04	3.2E-05	1.6E-04
10m	1.9E-04	4.5E-04	6.7E-05	3.4E-04	1.0E-04	2.4E-04	3.6E-05	1.8E-04
12m	2.1E-04	5.1E-04	7.6E-05	3.8E-04	1.2E-04	3.0E-04	4.4E-05	2.2E-04
14m	2.4E-04	5.7E-04	8.6E-05	4.3E-04	1.5E-04	3.6E-04	5.4E-05	2.7E-04
16m	2.7E-04	6.5E-04	9.7E-05	4.8E-04	1.9E-04	4.5E-04	6.7E-05	3.3E-04
18m	3.1E-04	7.3E-04	1.1E-04	5.5E-04	2.3E-04	5.5E-04	8.3E-05	4.2E-04
20m	3.4E-04	8.2E-04	1.2E-04	6.2E-04	2.9E-04	6.9E-04	1.0E-04	5.2E-04
22m	3.9E-04	9.3E-04	1.4E-04	7.0E-04	3.7E-04	8.8E-04	1.3E-04	6.6E-04
24m	4.4E-04	1.1E-03	1.6E-04	7.9E-04	4.7E-04	1.1E-03	1.7E-04	8.4E-04
26m	5.0E-04	1.2E-03	1.8E-04	8.9E-04	5.9E-04	1.4E-03	2.1E-04	1.1E-03
28m	5.6E-04	1.3E-03	2.0E-04	1.0E-03	7.6E-04	1.8E-03	2.7E-04	1.4E-03
30m	6.3E-04	1.5E-03	2.3E-04	1.1E-03	9.6E-04	2.3E-03	3.4E-04	1.7E-03
35m	8.2E-04	1.9E-03	2.9E-04	1.5E-03	1.5E-03	3.6E-03	5.4E-04	2.7E-03
40m	1.0E-03	2.5E-03	3.7E-04	1.9E-03	2.3E-03	5.5E-03	8.3E-04	4.2E-03
45m	1.3E-03	3.2E-03	4.7E-04	2.4E-03	3.2E-03	7.7E-03	1.2E-03	5.8E-03
50m	1.7E-03	4.0E-03	6.1E-04	3.0E-03	4.3E-03	1.0E-02	1.5E-03	7.7E-03
55m	2.1E-03	5.1E-03	7.6E-04	3.8E-03	5.7E-03	1.4E-02	2.0E-03	1.0E-02
60m	2.6E-03	6.2E-03	9.4E-04	4.7E-03	7.5E-03	1.8E-02	2.7E-03	1.3E-02
65m	3.2E-03	7.7E-03	1.2E-03	5.8E-03	9.9E-03	2.4E-02	3.5E-03	1.8E-02
70m	3.6E-03	8.7E-03	1.3E-03	6.5E-03	1.2E-02	2.8E-02	4.2E-03	2.1E-02
75m	4.1E-03	9.9E-03	1.5E-03	7.4E-03	1.4E-02	3.3E-02	5.0E-03	2.5E-02
80m	4.7E-03	1.1E-02	1.7E-03	8.4E-03	1.7E-02	4.0E-02	6.0E-03	3.0E-02
85m	5.3E-03	1.3E-02	1.9E-03	9.5E-03	2.0E-02	4.7E-02	7.1E-03	3.5E-02
90m	6.0E-03	1.4E-02	2.2E-03	1.1E-02	2.4E-02	5.6E-02	8.4E-03	4.2E-02
95m	6.9E-03	1.6E-02	2.5E-03	1.2E-02	2.8E-02	6.7E-02	1.0E-02	5.0E-02
100m	7.8E-03	1.9E-02	2.8E-03	1.4E-02	3.3E-02	8.0E-02	1.2E-02	6.0E-02
105m	8.8E-03	2.1E-02	3.2E-03	1.6E-02	4.0E-02	9.5E-02	1.4E-02	7.1E-02
110m	1.0E-02	2.4E-02	3.6E-03	1.8E-02	4.7E-02	1.1E-01	1.7E-02	8.5E-02
115m	1.1E-02	2.7E-02	4.1E-03	2.0E-02	5.6E-02	1.3E-01	2.0E-02	1.0E-01
120m	1.3E-02	3.1E-02	4.6E-03	2.3E-02	6.7E-02	1.6E-01	2.4E-02	1.2E-01

TABLE E-8.—EMISSIONS SCREENING LIMITS FOR CARCINOGENIC METALS FOR FACILITIES IN COMPLEX TERRAIN

Values for use in urban and rural areas	Terrain-adjusted effective stack height			
	Arsenic (g/sec)	Cadmium (g/sec)	Chromium (g/sec)	Beryllium (g/sec)
4m	3.1E-05	7.3E-05	1.1E-05	5.5E-05
6m	4.5E-05	1.1E-04	1.6E-05	8.1E-05
8m	6.6E-05	1.6E-04	2.4E-05	1.2E-04
10m	9.7E-05	2.3E-04	3.5E-05	1.7E-04
12m	1.2E-04	2.8E-04	4.2E-05	2.1E-04
14m	1.4E-04	3.5E-04	5.2E-05	2.6E-04
16m	1.7E-04	4.0E-04	6.0E-05	3.0E-04
18m	1.9E-04	4.4E-04	6.7E-05	3.3E-04
20m	2.1E-04	4.9E-04	7.4E-05	3.7E-04
22m	2.3E-04	5.4E-04	8.2E-05	4.1E-04
24m	2.5E-04	6.0E-04	9.0E-05	4.5E-04
26m	2.8E-04	6.7E-04	1.0E-04	5.0E-04
28m	3.1E-04	7.4E-04	1.1E-04	5.5E-04
30m	3.4E-04	8.2E-04	1.2E-04	6.1E-04
35m	4.3E-04	1.0E-03	1.5E-04	7.6E-04
40m	5.2E-04	1.3E-03	1.9E-04	9.4E-04
45m	6.5E-04	1.5E-03	2.3E-04	1.2E-03
50m	8.0E-04	1.9E-03	2.9E-04	1.4E-03
55m	9.8E-04	2.3E-03	3.5E-04	1.8E-03
60m	1.2E-03	2.9E-03	4.3E-04	2.2E-03
65m	1.5E-03	3.6E-03	5.3E-04	2.7E-03
70m	1.7E-03	4.0E-03	6.0E-04	3.0E-03
75m	1.9E-03	4.5E-03	6.7E-04	3.3E-03
80m	2.1E-03	5.0E-03	7.5E-04	3.7E-03
85m	2.3E-03	5.6E-03	8.4E-04	4.2E-03
90m	2.6E-03	6.3E-03	9.4E-04	4.7E-03
95m	2.9E-03	7.0E-03	1.1E-03	5.3E-03
100m	3.3E-03	7.8E-03	1.2E-03	5.9E-03
105m	3.7E-03	8.8E-03	1.3E-03	6.6E-03
110m	4.1E-03	9.8E-03	1.5E-03	7.4E-03
115m	4.6E-03	1.1E-02	1.7E-03	8.3E-03
120m	5.2E-03	1.2E-02	1.8E-03	9.2E-03

TABLE E-9.—FEED RATE SCREENING LIMITS FOR TOTAL CHLORINE

Terrain-adjusted effective stack height	Noncomplex Total chlorine (lb/hr)	Complex Total chlorine (lb/hr)
4m	2.0E−01	2.6E−01
6m	2.5E−01	2.7E−01
8m	3.0E−01	2.8E−01
10m	3.7E−01	2.9E−01
12m	4.7E−01	3.3E−01
14m	6.1E−01	3.8E−01
16m	7.8E−01	4.4E−01
18m	9.8E−01	5.0E−01
20m	1.2E+00	5.7E−01
22m	1.6E+00	6.5E−01
24m	2.0E+00	7.4E−01
26m	2.5E+00	8.4E−01
28m	3.1E+00	9.6E−01
30m	3.9E+00	1.1E+00
35m	5.7E+00	1.5E+00
40m	8.0E+00	2.1E+00
45m	1.1E+01	3.0E+00
50m	1.5E+01	4.1E+00
55m	1.9E+01	5.7E+00
60m	2.3E+01	8.0E+00
65m	2.7E+01	1.1E+01
70m	3.0E+01	1.2E+01
75m	3.3E+01	1.3E+01
80m	3.6E+01	1.4E+01
85m	4.0E+01	1.5E+01
90m	4.4E+01	1.7E+01
95m	4.9E+01	1.8E+01
100m	5.4E+01	2.0E+01
105m	5.9E+01	2.1E+01
110m	6.5E+01	2.3E+01
115m	7.2E+01	2.5E+01
120m	7.9E+01	2.7E+01

TABLE E-10.—EMISSIONS SCREENING LIMITS FOR HYDROGEN CHLORIDE

Terrain-adjusted effective stack height	Noncomplex HCl (g/sec)	Complex HCl (g/sec)
4m	2.6E−02	3.3E−02
6m	3.1E−02	3.4E−02
8m	3.8E−02	3.5E−02
10m	4.6E−02	3.7E−02
12m	6.0E−02	4.2E−02
14m	7.7E−02	4.8E−02
16m	9.9E−02	5.5E−02
18m	1.2E−01	6.3E−02
20m	1.6E−01	7.2E−02
22m	2.0E−01	8.2E−02
24m	2.5E−01	9.3E−02
26m	3.1E−01	1.1E−01
28m	3.9E−01	1.2E−01
30m	4.9E−01	1.4E−01
35m	7.2E−01	1.9E−01
40m	1.0E+00	2.7E−01
45m	1.4E+00	3.7E−01
50m	1.9E+00	5.2E−01
55m	2.4E+00	7.2E−01
60m	2.9E+00	1.0E+00
65m	3.4E+00	1.4E+00
70m	3.8E+00	1.5E+00
75m	4.2E+00	1.7E+00
80m	4.6E+00	1.8E+00
85m	5.1E+00	1.9E+00
90m	5.6E+00	2.1E+00
95m	6.1E+00	2.3E+00
100m	6.8E+00	2.5E+00
105m	7.5E+00	2.7E+00
110m	8.2E+00	2.9E+00
115m	9.1E+00	3.2E+00
120m	1.0E+01	3.5E+00

Appendix F: Technical Support for Tier I-III Metals and HCL Controls and THC Emissions Rate Screening Limits

This appendix summarizes the risk assessment approach the Agency used to develop the proposed Tier I and II Screening Limits for metals and HCl, and the emission rate Screening Limits for total hydrocarbons (THC) that would be used to assess THC emissions under the health-based Tier II alternative for PIC controls. In addition, the appendix summarizes how the metals and HCl controls would be implemented.

I. Overview of EPA's Risk Assessment

The risk assessment methodology is discussed in detail in the background document supporting the amendments EPA plans to propose shortly for hazardous waste incinerators— Technical Background Document: Controls for Metals and Hydrogen Chloride Emissions for Hazardous Waste Incinerators. As explained in the text of today's notice, the emissions standards, technical support, and risk assessment methodology for the boiler/ furnace rules are identical to those the Agency plans to propose for incinerators. The methodology is summarized below for the convenience of the reader.

A. Overview of the Risk Assessment Approach

EPA's risk assessment approach involves: (1) Establishing ambient levels of pollutants (i.e., metals, hydrogen chloride (HCl), and total hydrocarbons (THC)) that pose acceptable health risk; and (2) developing conservative dispersion coefficients [40] for reasonable worst-case facilities as a function of key parameters (i.e., effective stack height,[41] terrain type, and land use classification). To establish the conservative Screening Limits for metals, HCl, and THC, we back-calculated from the acceptable ambient levels using the conservative dispersion coefficients.

Under today's proposal, applicants would be required to demonstrate that emissions of metals, HCl, and (when stack gas CO concentrations exceed 100 ppmv and under the health-based alternative approach to assess THC emissions) THC emissions do not result in an exceedance of the acceptable ambient levels. If the conservative Screening Limits are not exceeded,

applicants need not conduct site-specific dispersion modeling to make this demonstration.

B. Development of Conservative Dispersion Coefficients

1. *Factors Influencing Ambient Levels of Pollutants.* Ambient levels of pollutants resulting from stack emissions are a function of the dispersion of pollutants from the source in question. Many factors influence the relationships between releases (emissions) and ground-level concentrations, including: (1) The rate of emission; (2) the release specifications of the facility (i.e., stack height, exit velocity, exhaust temperature and inner stack diameter, which together define the facility's "effective stack height"); (3) local terrain; and (4) local meteorology and (5) urban/rural classification.

2. *Selection of Facilities and Sites for Dispersion Modeling.*[42] Hazardous waste incinerators are known to vary widely in capacity, configuration, and design, making it difficult to identify typical parameters that affect dispersion of emissions (i.e., release parameters). For instance, stack heights of incinerators listed in the 1981 mail survey [43] vary from less than 15 feet to over 200 feet. Futhermore, many new facilities that are now in operation that are not listed on the survey, and EPA expects that a large number of additional facilities of various types of designs are likely to be constructed over the next several years.

For currently operating facilities, the worst-case dispersion situation would be a combination of release specifications, local terrain, urban/rural land use classification, and local meteorology that produces the highest ambient concentrations of hazardous pollutants per unit of pollutant released by a facility. This can be expressed, for any specific facility, as a dispersion coefficient, which, for purposes of this proposal, is the maximum annual average (or, as explained later, for HCl, maximum 3-minute) ground-level concentration for an emission of 1 g/s (a

unit release); the units of the dispersion coefficient are, therefore, $\mu g/m^3/g/s$.[44]

Since dispersion coefficients are, as a general rule, inversely correlated with effective stack heights, worst-case facilities are most likely to be those with the shortest effective stack heights. No similar *a priori* judgment, however, should be made with respect to terrain or meteorology; evaluation of the influence of these factors requires individual site-by-site dispersion modeling. It was therefore not possible to screen facility locations in advance to select for probable worst-case situations simply by considering stack height.

Instead, out of a total number of 154 existing facilities for which data were available from the 1981 mail survey,[45] we roughly sorted the facilities into three terrain types based on broad-scale topographic maps: flat, rolling, and complex terrain. We then ranked the facilities by effective stack heights. Next, we evaluated terrain rise out to 50 km for each of the 24 facilities and ranked the facilities by maximum terrain rise. Finally, we subdivided the 24 facilities into three groups which are loosely defined as flat, rolling, and complex terrain. In addition, to enable us to determine conservative dispersion coefficients as a function of effective height, we developed 11 hypothetical incinerators and modeled each of these "incinerators" at the 24 sites. The hypothetical facilities were selected by dividing the range of facilities listed in the 1981 survey into 10 categories based on effective stack height. Then, within each stack height category, we selected a hypothetical effective stack height that approximated the 25th percentile of the range of heights that existed within the category. The 25th percentile was chosen in order to select a facility likely to reflect the higher end of dispersion coefficients (and ambient levels) in each height category. In addition, an eleventh hypothetical source was defined in order to represent facilities whose heights of release do not meet good engineering practice (see the discussion on good engineering practice in Section II of this appendix). Such devices will

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[40] For purposes of this document, the term dispersion coefficient refers to the ambient concentration that would result from an emission rate of 1 gram/sec.

[41] Effective stack height is the height above ground level of a plume, based on summing the physical stack height plus plume rise.

[42] A survey of hazardous waste incinerators was used to identify the range of release parameters— stact height, plume rise—representative of the universe of incinerators. These release parameters were used to develop the conservative dispersion coefficients that were used to develop the Screening Limits. Given that the range of incinerator release parameters will also represent the range of release parameters for boilers and industrial furnaces, the Screening Limits will also be appropriated for boilers and furnaces (U.S. EPA, Draft Technical Background Document for Control of Metals and HCl Emissions from Hazardous Waste Incinerators, August 1989).

[43] DPRA, op. cit.

[44] Dispersion coefficients can be defined for any specific location surrounding a release. The maximum dispersion coefficient will, under the assumptions used in this regulation, be the dispersion coefficient for the MEI. It may occur at any distance and in any direction from the facility. However, locations within the property boundary of a facility would not be considered when implementing these proposed rules unless individuals reside on site.

[45] We note that the survey should be representative because it addressed over 50 percent of the 250 hazardous waste incinerators now in operation.

experience "building wake effects"—turbulence created by adjacent structures that immediately mixes the plume resulting in high ground level concentrations close to the stack.

Finally, we also included the site that resulted in the worst-case complex terrain conditions during development of the rule for boilers and industrial furnaces in 1987.[46] Although there is currently no hazardous waste incinerator at that site, we used the site as another theoretical location for the 11 hypothetical incinerators and merged the results into those from the actual incinerator sites. Under certain conditions, this site provided higher dispersion coefficients for some stacks.

In summary, 11 hypothetical incinerators and the actual incinerators were modeled at each of 24 sites evenly distributed among flat, rolling, and complex terrain. In addition, the 11 hypothetical incinerators were modeled at an additional complex terrain site.

3. *Development of Dispersion Coefficients.* Estimating the air impacts of the facilities required the use of five separate air dispersion models. We used the *"EPA Guideline on Air Quality Models (Revised),"* [47] and consulted with the EPA Office of Air Quality Planning and Standards to select the most appropriate model for each application.

For each of the 25 locations, five consecutive years of concurrent surface and twice-per-day upper air data (to characterize mixing height) were acquired. The data sets contained hourly records of surface observations for five years, or approximately 44,000 consecutive hours of meteorological data. The same five-year data set was used to estimate the highest hourly dispersion coefficient during the five-year period, and to estimate annual average concentrations based on a five year data set for all release specifications modeled at each location.

The actual incinerator release specifications at each location were used to select the appropriate model for short-term and long-term averaging periods. Once selected, the release specifications for the actual incinerator and the 11 hypothetical incinerators

were modeled. Table F-1 lists the models selected.

TABLE F-1.—MODELS SELECTED FOR THE RISK ANALYSIS

Terrain classification	Urban/rural	Averaging period	Model selected
Flat or Rolling.	Urban or Rural.	Annual average.	ISCLT.
Flat or Rolling.	Urban or Rural.	Hourly	ISCST.
Complex	Urban............	Annual average.	LONGZ.
Complex	Urban............	Hourly	SHORTZ.
Complex	Rural	Hourly or annual.	COMPLEX I.

The Industrial Source Complex models (ISCLT and ISCST) were selected for flat and rolling terrain because they can address building downwash or elevated releases and can account for terrain differences between sources and receptors. The long-term mode (ISCLT) was used for annual averages, while the short-term mode (ISCST) was used to estimate maximum hourly concentrations.

To meet the EPA guidance on model selection, we used three different models to characterize dispersion over complex terrain. For urban applications, OAQPS recommends SHORTZ for short-term averaging periods and LONGZ for seasonal or annual averages. For rural sites located in complex terrain, OAQPS recommends the COMPLEX I model.

We used U.S. Geological Survey 7.5-minute topographic maps to document terrain rise out to 5 km from each stack. For purposes of this proposed rule, a facility is considered to be in flat terrain if the maximum terrain rise within 5 km of the stack is not greater than 10 percent of the physical stack height. The facility is in rolling terrain if terrain rise is greater than 10 percent but not greater than the physical stack height, and in complex terrain if terrain rise is greater than the physical stack height.[48]

We also used the topographic maps as the basis to classify land use as urban or rural. A simplified version of the Auer technique [49] based on the preferred land

use approach (rather than population density) was used for this classification. If greater than 50 percent of the land was classified as urban, the models were executed in the urban mode for that facility. If greater than 50 percent was classified as rural, the rural modes were used.[50]

To identify conservative dispersion coefficients as a function of effective stack height, we graphically plotted for each terrain type (i.e., flat, rolling, and complex) and each land use classification (i.e., urban and rural) dispersion coefficients for the modeled facilities and locations as a function of effective stack height. The outer envelope representing the highest dispersion coefficients was drawn to enable us to identify conservative coefficients for any effective stack height within the range of those modeled (i.e., 4 m to 120 m).

We determined that there was no significant difference in dispersion coefficients (under the severe conditions modeled) betwen flat and rolling terrain. Thus, those terrain types were merged together and termed noncomplex terrain. In addition, a discontinuity was observed between the SHORTZ/LONGZ and Complex I [51] models, which resulted in our not distinguishing between land use classifications in complex terrain. Finally, we note that there was no significant difference in 3-minute exposures between urban and rural land used in either noncomplex or complex terrain. Thus, we have not distinguished between land use classifications in establishing the HCl Screening Limits. There is, however, a significant difference in maximum annual average dispersion coefficients between urban and rural land use in noncomplex terrain, and so we have established separate metals and THC Screening Limits for those situations.

We note that the dispersion coefficients used to establish the Screening Limits are designed to be conservative, but may, in fact, not be conservative in extremely poor dispersion conditions, or when the receptor (location (i.e., residence)) is close-in to the source. Under the

[46] See "Background Information Document for the Development of Regulations to Control the Burning of Hazardous Waste in Boilers and Industrial Furnaces, Volume III: Risk Assessment, Engineering-Sciences", February 1987. (Available from the National Technical Information Service, Springfield, VA. Order No. PB 87 173845.)

[47] USEPA."*Guideline on Air Quality Models (Revised)*." U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. EPA-450/2/78-027R. July 1986.

[48] We note that EPA can consider terrain well past 5 km of a stack to define terrain type for some facilities. We believe, however, that a radius of 5 km is adequate because we are concerned with MEI exposures (as opposed to aggregate population exposures) and because the effective stack heights of concern are relatively low in comparison to facilities such as major power plants. Thus, MEI exposures for the conditions modeled will always occur within 5 km of the stack.

[49] Auer, August, H., Jr. "*Correlation of Land Use and Cover with Meteorological Anomalies. Journal of Applied Meteorology*"; Vol. 17, pp. 636-643, May 1978.

[50] OAQPS guidelines indicate that 50 percent is the cutoff point between urban and rural; however, to be conservative and to account for differences in the accuracy of different measurement methods, EPA is recommending that for permitting purposes land use be considered urban if greater than 75 percent is urban; that it be considered rural if land use is greater than 75 percent rural; and that if the land use is between 75 percent urban and 75 percent rural the more conservative Screening Limit of the two be used.

[51] Complex I was found to produce relatively low estimates of short-term concentrations.

situations identified below, the Screening Limits may not be protective and the permit writer should require site-specific dispersion modeling consistent with EPA's *"Guideline on Air Quality Models (Revised)"* to demonstrate that emissions do not pose unacceptable health risk:

• Facility is located in a narrow valley less than 1 km wide; or

• Facility has a stack taller than 20 m and is located such that the terrain rises to the stack height within 1 km of the facility; or

• Facility has a stack taller than 20 m and is located within 5 km of the shoreline of a large body of water (such as an ocean or large lake); or

• The facility property line is within 200 m of the stack and the physical stack height is less than 10 m; or

• Onsite receptors are of concern, and the stack height is less than 10 m.

In addition to the situations identified above, there is a probability, albeit small, that the combination of critical parameters, stack height, stack gas velocity, effluent temperature, meteorological conditions, etc., will result in higher ambient concentrations than resulted from the conservative modeling done to support this rule. As a result, the Agency is reserving the right to require that the owner or operator submit, as part of the permit proceeding, an air quality dispersion analysis consistent with EPA's *"Guideline on Air Quality Models (Revised)"* in order to ensure that acceptable ambient levels of pollutants are not exceeded irrespective of whether the facility meets the specific Screening Limits that would be established by this regulation.

Finally, we specifically request comment on whether less conservative assumptions, coupled with a safety factor then applied to assure that ambient levels are not underestimated, should be used to develop the Screening Limits. This alternative approach may have merit because the repeated use of conservative assumptions in an analysis may "multiply" the conservatism unreasonably. Comments are solicited on: (1) The extent to which less conservative assumptions would enable applicants to meet the Limits and, thus, how to reduce the conservatism of the Screening Limits while still ensuring that they are protective; and (3) how the reduced conservatism would affect the criteria discussed above that must be considered to determine if the Screening Limits are protective for a particular situation.

C. Evaluation of Health Risk

1. *Risk from Carcinogens.* EPA cancer risk policy suggests that any level of human exposure to a carcinogenic substance entails some finite level of risk. Determining the risk associated with a particular dose requires knowing the slope of the modeled dose-response curve. On this basis, EPA's Carcinogen Assessment Group (CAG) has estimated carcinogenic slope factors for humans exposed to known and suspected human carcinogens. Slope factors are estimated by a modeling process. The slope of the dose-response curve enables estimation of a unit risk. The unit risk is defined as the incremental lifetime risk estimated to result from exposure of an individual for a 70-year lifetime to a carcinogen in air containing 1 microgram of the compound per cubic meter of air. Both the slope factors and unit risks are reviewed by the Agency's Cancer Risk Assessment Validation Endeavor (CRAVE) workgroup for verification.

In setting acceptable risk levels to develop today's proposed rule, we considered the fact that not all carcinogens are equally likely to cause human cancers, as discussed in *"Guidelines for Carcinogenic Risk Assessment"* (51 FR 33992 [September 24, 1986]). The Guidelines have established a weight-of-evidence scheme reflecting the likelihood that a compound causes tumors in humans. The weight-of-evidence scheme categorizes carcinogens according to the quantity and quality of both human and animal data as known, probable, and possible human carcinogens. The proposed approach places a higher weight on cancer unit risk estimates that are based on stronger evidence of carcinogenicity. The proposed approach will provide for making fuller use of information by explicitly examining risk for different categories of carcinogens. In reaching the conclusion of the level of cancer risks to be used to support this proposal, we have considered available information on the constituents being emitted, the evidence associating these compounds with cancer risk, the quantities of emissions of these constituents, and the exposed populations.

For purposes of today's notice, we are proposing the following risk levels as acceptable incremental lifetime cancer risk levels to the hypothetical maximum exposed individual (MEI): (1) for Group A and B carcinogens, on the order of 10^{-6},[52] and (2) for Group C carcinogens,

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[52] A dose is calculated to correspond to a risk of causing cancer to one individual in one million exposed to that dose over a lifetime.

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on the order of 10^{-5}. These risk levels are within the range of levels historically used by EPA in its hazardous waste and emergency response programs—10^{-4} to 10^{-7}.

Under the weight-of-evidence approach to assess carcinogenic risk for this proposed rule, we believe it is appropriate to add the risk from carcinogens *within* the category of those that are known or probable human carcinogens, the Group A and B carcinogens. Such a group is composed of certain metals which cause lung cancer (arsenic, beryllium, cadmium, and chromium).

Similarly, it is appropriate to add the risk from carcinogens within the category of those that are probable or possible human carcinogens, C carcinogens.

To implement this carcinogenic risk assessment approach, we are proposing to limit the aggregate risk to the MEI to 10^{-5}. Given that the carcinogenic metals that would be regulated in today's proposed rule are all Group A or B carcinogens, this approach would effectively limit the risk from individual carcinogenic metals to levels on the order of 10^{-6} but below 10^{-5}. We considered limiting the aggregate risk to the MEI to 10^{-6} but determined that it would result in setting risk levels for individual carcinogens to levels on the order of 10^{-7}, which has been judged (for purposes of this rule) to be unnecessarily conservative, considering the relatively low projected cancer incidence and relatively high cost per cancer reduced. Even though the cancer incidence is low, we do not consider a 10^{-4} risk level acceptable because: (1) The total annualized cost of the rule at a 10^{-5} aggregate risk level is not substantial; thus, the cost of the added margin of safety is reasonable; (2) indirect exposure has not yet been considered; and (3) toxic compounds not yet identified are not being controlled directly in this rulemaking. We believe that an aggregate MEI risk of 10^{-5} is appropriate because: (1) It provides adequate protection of public health; (2) it considers weight of evidence of human carcinogenicity; (3) it limits the risk from individual Group A and B carcinogens to risk levels on the order of 10^{-6}; and (4) It is within the range of risk levels the Agency has used for hazardous waste regulatory programs.

The Agency would like to use the weight-of-evidence approach in developing the health-based alternative approach to assessing THC emissions under the Tier II PIC controls. However, there a number of unidentified compounds in the mix of hydrocarbon

emissions. These unidentified compounds could be either carcinogens or noncarcinogens, or both. Of the compounds that may be carcinogens, the Agency does not know whether they would be classified as A, B1, B2, or C carcinogens. Since the Agency cannot classify these unknown carcinogens, the Agency is unable to use a weight-of-evidence approach to select an acceptable risk level for THC. In order to be conservative, the Agency is assuming that THC can be treated as a single compound for which a unit cancer risk is calculated. To derive this unit cancer risk value, the historical data base of THC emissions from hazardous waste incinerators, boilers, and industrial furnaces was used. For each organic compound identified in the emissions, the 95th percentile highest concentration value was taken as a reasonable worst-case value. (The highest concentration was often used because there were too few data to identify the 95th percentile value.) For organic compounds listed in Appendix VIII of Part 261 for which health effects data are adequate to establish an RSD or RAC, but which have not been detected in emissions from hazardous waste combustion, an arbitrary emission concentration of 0.1 ng/L was assumed. The data base was further adjusted to increase the conservatism of the calculated THC unit risk value by assuming that the carcinogen formaldehyde is emitted from hazardous waste combustion devices at the 95th percentile levels found to be emitted from municipal waste combustors. The proportion of the emission concentration of each compound to the total emission concentration for all compounds was then determined. This proportion, termed a proportional emission concentration, was them multiplied by the unit cancer risk developed by CAG to obtain a risk level for that compound. A unit risk of zero was used for noncarcinogens like methane. All the cancer risks were added together to derive a weighted average 95th percentile unit risk value for THC. This procedure for developing a THC unit risk value assumes that the proportion of the various hydrocarbons is the same for all incinerators, boilers and industrial furnaces burning hazardous waste. In addition, it weighs all carcinogens the same regardless of current EPA classification.

As explained in the text, we are proposing to limit hydrocarbon emissions—when stack gas carbon monoxide levels exceed 100 ppmv and under the health-based alternative—based on a 10^{-5} aggregate risk level.

Thus, we are limiting each of the constituents to a risk level on the order of 10^{-6}.

Finally, in assessing the risk from facilities that emit both THC and carcinogenic metals, we are not proposing that the risk from THC emissions be added to the aggregate MEI risk from metals emissions. Adding the risk would be inappropriate because we do not know how all the THC would be classified according to weight of evidence. (We note again that we prefer the technology-based approach to assess THC emissions for reasons discussed in the text.)

We specifically request comment on this proposed approach to assess carcinogenic risk. We also welcome suggestions or alternative ways to account for additivity.

The Agency also requests comment on whether aggregate population risk or cancer incidence (i.e., cancer cases per year) should also be considered in developing the national emission limits and in site-specific risk assessments. This approach could, in some situations, be more conservative than considering only MEI risk because, even if the "acceptable" MEI risk level were not exceeded, large population centers may be exposed to emissions such that the increase in cancer cases could be significant. However, it would be difficult to develop acceptable aggregate cancer incidence rates. Nevertheless, it is likely that many facilities that perform a site-specific MEI exposure and risk analysis would also generate an aggregate population exposure and risk analysis that could be considered by the Agency. Based on public comment and further thought on how to implement this dual approach, the final rule could incorporate consideration of both the MEI and aggregate population risk. Alternatively, EPA could provide guidance to the permit writer on when and how to consider cancer incidence on a case-by-case basis under authority of section 3005(c)(3) of HSWA, as codified at § 270.32(b)(2).

2. *Risk from Noncarcinogens.* For toxic substances not known to display carcinogenic properties, there appears to be an identifiable exposure threshold below which adverse health effects usually do not occur. Noncarcinogenic effects are manifested when these pollutants are present in concentrations great enough to overcome the homeostatic, compensating, and adaptive mechanisms of the organism. Thus, protection against the adverse health effects of a toxicant is likely to be achieved by preventing total exposure levels from exceeding the threshold

dose. Since other sources in addition to the controlled source may contribute to exposure, ambient concentrations associated with the controlled source should ideally take other potential sources into account. The Agency has therefore conservatively defined reference air concentrations (RACs) for noncarcinogenic compounds that are defined in terms of a fixed fraction of the estimated threshold concentration. The RACs for lead and hydrogen chloride, however, were established differently, as discussed below. The RACs are presented in Appendix H to this notice.

RACs have been derived from oral reference doses (RfDs) for those noncarcinogenic compounds listed in Appendix VIII of 40 CFR Part 261 (except for lead and hydrogen chloride) for which the Agency considers that it has adequate health effects data. An oral RfD is an estimate (with an uncertainty of perhaps an order of magnitude) of a daily exposure (via ingestion) for the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects even if exposure occurs daily for a lifetime. Since these oral-based RACs are subject to change, EPA contemplates publishing **Federal Register** notices if the RACs change in a way that affects the regulatory standard (see also the discussion of this issue in the **Federal Register** notice on boilers and furnaces published today).

The Agency is proposing RACs derived from oral RfDs because it believes that the development of the RfDs has been technically sound and adequately reviewed. Specifically:

1. EPA has developed verified RfDs and is committed to establishing RfDs for all constituents of Agency interest. The verification process is conducted by an EPA workgroup, and the conclusions and reasons for these decisions are publicly available.

2. The verification process ensures that the critical study is of appropriate length and quality to derive a health limit for long-term, lifetime protection.

3. RfDs are based on the best available information meeting minimum scientific criteria. Information may come from experimental animal studies or from human studies.

4. RfDs are designed to give long-term protection for even the most sensitive members of the population, such as pregnant women, children, and older men and women.

5. RfDs are designated by the Agency as being of high, medium, or low confidence depending on the quality of the information on which they are based

and the amount of supporting data. The criteria for the confidence rating are discussed in the RfD decision documents.

The Agency used the follwing strategy to derive the inhalation exposure limits proposed today:

1. Where a verified oral RfD has been based on an inhalation study, we will calculate the inhalation exposure limit directly from the study.

2. Where a verified oral RfD has been based on an oral study, we will use a conversion factor of 1 for route-to-route extrapolation in driving an inhalation limit.

3. Where appropriate EPA health documents exist, such as the Health Effects Assessments (HEAs) and the Health Effects and Environmental Profiles (HEEPs), containing relevant inhalation toxicity data, their data will be used in deriving inhalation exposure limits. We will also consider other agency health documents (such as NIOSH's criteria documents).

4. If RfDs or other toxicity data from agency health documents are not available, then we will consider other sources of toxicity information. Calculations will be made in accordance with the RfD methodology.

The Agency recognizes the limitations of route-to-route conversions used to derive the RACs and is in the process of examining confounding factors affecting the conversion, such as: (a) The appropriateness of extrapolating when a portal of entry is the critical target organ; (b) first pass effects; and (c) effect of route on dosimetry.

The Agency, through its Inhalation RfD Workgroup, is developing reference dose values for inhalation exposure, and additional values are expected to be available this year. The Agency will use the available inhalation RfDs—after providing appropriate opportunity for public comment—when this rule is promulgated. Certainly, if the workgroup develops inhalation reference doses prior to promulgation of today's rule that are substantially different from the RACs proposed today, and if the revised inhalation reference dose could be expected to have a significant adverse impact on the regulated community, the Agency will take public comment on the revised RACs after notice in the Federal Register.

EPA proposed this same approach for deriving RACs on May 6, 1987 (52 FR 16993) for boilers and industrial furnaces burning hazardous waste. We received a

number of comments on the proposed approach of deriving reference air concentrations (RACs) from oral RfDs. As stated in today's proposal and the May 6, 1987, proposal, we would prefer to use inhalation reference doses. Some comments suggested other means of deriving RACs. We will consider those comments and others that may be submitted as a result of today's notice in developing the final rule.

As previously stated, EPA has derived the RACs from oral reference doses (RfDs) for the compounds of concern. An oral RfD is an estimate of a daily exposure (via ingestion) for the human population that is likely to be without an appreciable risk of deleterious effects, even if exposure occurs daily throughout a lifetime.[53] The RfD for a specific chemical is calculated by dividing the experimentally determined no-observed-adverse-effect-level (NOAEL) or lowest-observable-adverse-effect-level (LOAEL) by the appropriate uncertainty factor(s). The RAC values inherently take into account sensitive populations.

The Agency is proposing to use the following equation to convert oral RfDs to RACs:

$$RAC \ (mg/m^3) = \frac{RfD \ (mg/kg\text{-}bw/day) \times body \ weight \times correction \ factor \times background \ level \ factor}{m^3 \ air \ breathed/day}$$

where:

• RfD is the oral reference dose

• Body weight (bw) is assumed to be 70 kg for an adult male

• Volume of air breathed by an adult male is assumed to be 20 m^3 per day

• Correction factor for route-to-route extrapolation (going from the oral route to the inhalation route) is 1.0

• Background level factor is 0.25. It is a factor to fraction the RfD to the intake resulting from direct inhalation of the compound emitted from the source (i.e., an individual is assumed to be exposed to 75 percent of the RfD from the combination of indirect exposure from the source in question and other sources).

a. *Short-Term Exposures.* In today's proposed rule, the RACs are used to determine if adverse health effects are likely to result from exposure to stack emissions by comparing maximum

annual average ground-level concentrations of a pollutant to the pollutant's RAC. If the RAC is not exceeded, EPA does not anticipate adverse health effects. The Agency, however, is also concerned about the impacts of short-term (less than 24-hour) exposures. The ground-level concentration of an emitted pollutant can be an order of magnitude greater during a 3-minute or 15-minute period of exposure than the maximum annual average exposure. This is because meteorological factors vary over the course of a year resulting in a wide distribution of exposures. Thus, maximum annual average concentrations are always much lower than short-term exposure concentrations. On the other hand, the short-term exposure RAC is also generally much higher than the lifetime exposure RAC. Nonetheless, in some

cases short-term exposure may pose a greater health threat than annual exposure. Unfortunately, the use of RfDs limits the development of short-term acute exposure limits because no acceptable methodology exists for the derivation of less than lifetime exposure from the RfDs.[54] However, despite these limitations, the Agency is proposing a short-term (i.e., 3-minute) RAC for HCl of 150 mg/m^3, based on limited data documenting a no-observed-effect-level in animals exposed to HCl via inhalation.[55] We do anticipate, however, that short-term RACs for other compounds will be developed by the Agency in the future.

[53] Current scientific understanding, however, does not consider this demarcation to be rigid. For brief periods and for small excursions above the RfD, adverse effects are unlikely in most of the population. On the other hand, several

circumstances can be cited in which particularly sensitive members of the population suffer adverse responses at levels well below the RfD. See 51 FR 1627 (January 14, 1986).

[54] Memo from Clara Chow through Reva Rubenstein, Characterization and Assessment Division, EPA, to Robert Holloway, Waste Management Division, EPA, entitled "Use of RfDs Versus TLVs for Health Criteria," January 13, 1987.
[55] Memo from Characterization and Assessment Division to Waste Management Division, October 2, 1986, interpreting results from Sellakumar, A.R.; Snyder, C.A.; Solomon, J.J.; Albert, R.E. (1985) "Carcinogenicity of Formaldehyde and Hydrogen Chloride in Rats. Toxicol. Appl. Pharm." 81:401–406.

b. *RAC for HCl.* The RAC for annual exposure to HCl is 7 µg/m [56] and is based on the threshold of its priority effects. Background levels were considered to be insignificant given that there are not many large sources of HCl and that this pollutant generally should not be transported over long distances in the lower atmosphere. The RAC for 3-minute exposure is 150 µg/m³.[57] We note that EPA proposed an annual exposure RAC for HCl of 15 µg/m³ in the 1987 boiler and furnace proposed rule. See 52 FR 16994. The Agency's inhalation Rfd workgroup has recently determined, however, that the annual exposure RAC should be 7 µg/m³.

c. *RAC for Lead.* To consider the health effects from lead emissions, we adjusted the National Ambient Air Quality Standard (NAAQS) by a factor of one-tenth to account for background ambient levels and indirect exposure from the source in question. In addition, the Agency has recently determined that lead is a probable human carcinogen even though a unit risk value has not yet been developed. Although the lead NAAQS is 1.5 µg/m³, sources could contribute only up to 0.15 µg/m³ for purposes of this regulation. Given, however, that the lead NAAQS is based on a quarterly average, the equivalent annual exposure is 0.09 µg/m³ for a quarterly average of 0.15 µg/m³. Thus, the lead RAC is 0.09 µg/m³. This is the same level EPA proposed in the 1987 boiler and furnace proposed rule. See 52 FR 17006.

d. *Relationship to NAAQS.* The Clean Air Act (CAA) requires EPA to establish ambient standards for pollutants determined to be injurious to public health or welfare. Primary National Ambient Air Quality Standards (NAAWS) must reflect the level of attainment necessary to protect public health allowing for an adequate margin of safety. Secondary NNAQS must be designed to protect public welfare in addition to public health, and, thus, are more stringent.

As discussed above, the Reference Air Concentration (RAC) proposed today for Lead is based on the Lead NAAQS. As the Agency develops additional NAAQS for toxic compounds that may be emitted from hazardous waste incinerators, boilers, and industrial furnaces, we will consider whether the acceptable ambient levels (and,

subsequently, the feed rate and emission rate Screening Limits) ultimately established under this rule should be revised.

The reference air concentration values (and risk-specific dose values for carcinogens) proposed here in no way preclude the Agency from establishing NAAQS as appropriate for these compounds under authority of the CAA.

D. Risk Assessment Assumptions

We have used a number of assumptions in the risk assessment, some conservative and others nonconservative, to simplify the analysis or to address issues where definitive data do not exist.

Conservative assumptions include the following:

• Individuals reside at the point of maximum annual average and (for HCl) maximum short-term ground-level concentrations. Furthermore, risk estimates for carcinogens assume that the maximum exposed individual resides at the point of maximum annual average concentration for a 70-year lifetime.

• Indoor air contains the same levels of pollutants contributed by the source as outdoor air.

• For noncarcinogenic health determinations, background exposure already amounts to 75 percent of the RfD. This includes other routes of exposure, including ingestion and dermal. Thus, the incinerator is only allowed to contribute 25 percent of the RfD via direct inhalation. The only exception is for lead, where the source is allowed to contribute only 10 percent of the NAAQS. This is because ambient lead levels in urban areas already represent a substantial portion (e.g., one-third or more) of the lead NAAQS. In addition, the Agency is particularly concerned about health risks from lead in light of health effects data available since the lead NAAQS was established. EPA is currently reviewing the lead NAAQS to determine if it should be lowered.[58]

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[58] At this point, we have not attempted to quantify indirect exposure through the food chain, ingestion of water contaminated by deposition, and dermal exposure, because as yet no acceptable methodology for doing so has been developed and approved by the Agency for use for evaluating combustion sources. We note, however, that by allowing the source to contribute only 25 percent of the RfD (or 10 percent of the NAAQS in the case of lead) accounts for indirect exposure by assuming a person is exposed to 75 percent of the RfD from other sources and other exposure pathways. (EPA is developing such a methodology for application to waste combustion sources. The Agency's Science Advisory Board has reviewed this methodology, and the Agency is continuing to refine the methodology. When the Agency completes development of procedures to evaluate indirect

• Risks are considered for pollutants that are known, probable, and possible human carcinogens.

• Individual health risk numbers have large uncertainty factors implicit in their derivation to take into effect the most sensitive portion of the population.

Nonconservative assumptions include the following:

• Although emissions are complex mixtures, interactive effects of threshold or carcinogenic compounds have not been considered in this regulation because data on such relationships are inadequate.[59]

• Environmental effects (i.e., effects on plants and animals) have not been considered because of a lack of adequate information. Adverse effects on plants and animals may occur at levels lower than those that cause adverse human health effects. (The Agency is also developing procedures and requesting Science Advisory Board review to consider environmental effects resulting from emissions from all categories of waste combustion facilities.)

II. *Implementation of the Metals and HCl Controls*

A.

Overview

As in the 1987 proposed rule, EPA is proposing to control metals and HCl emissions by requiring a site-specific risk analysis when metals or HCl emissions (or feed rates) exceed conservative Screening Limits. EPA developed the Screening Limits to minimize the need for conducting site-specific risk assessments, thereby reducing the burden to applicants and permit officials. When the Screening Limits are exceeded, the applicant would be required to conduct a site-specific risk assessment that demonstrates that the potential exposure of the maximum exposed individual to metals and HCl does not result in an exceedance of reasonable acceptable marginal additional risks, namely:

• That exposure to all carcinogenic metals be limited such that the sum of the excess risks attributable to ambient concentrations of these metals does not exceed an additional lifetime individual risk (to the (potential) maximum exposed individual) of 10^{-5}; and

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exposure, a more detailed analysis may be applied to all devices burning hazardous wastes.)

[59] Additive effects of carcinogenic compounds are considered by summing the risks for all carcinogens to estimate the aggregate risk to the most exposed individual (MEI).

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[56] Memo from Craig McCormack, EPA, to Dwight Hlustick, EPA, entitled "Environmental Exposure Limit Assessment for Hydrogen Chloride," July 1986.

[57] Memo from Lisa Ratcliff, EPA, to Dwight Hlustick, EPA, entitled "Short-term Health-based Number for Hydrogen Chloride," September 15, 1986.

• That exposure to each noncarcinogenic metal and HCl be limited such that exposure (to the (potential) maximum exposed individual) does not exceed the reference air concentration (RAC) for the metal and HCl.

B. Meals and HCl Emissions Standards

The metals and HCl emissions standards would require site-specific risk assessment to demonstrate that emissions will not: (1) Result in exceedances of the reference air concentrations (RACs) for noncarcinogens at the potential MEI; and (2) result in an aggregate increased lifetime cancer risk to the potential MEI of greater than 1×10^{-5}. The RACs for noncarcinogens and risk specific doses (RSDs) for carcinogens are presented in appendix H to this notice.

To reduce the burden on applicants and permitting officials, EPA has developed conservative Screening Limits for metals and HCl emissions (and feed rates) as a function of terrain adjusted effective stack height, terrain, and land use. See discussion below. If the Screening Limits are not exceeded, site-specific dispersion modeling would not be required to demonstrate conformance with the proposed standard.

If the Screening Limits are exceeded, the applicant would be required to conduct site-specific dispersion modeling in conformance with "Guideline on Air Quality Models (Revised)," July 1986, EPA Publication Number 450/2-78-027R (OAQPS Guideline No. 1.2-080), available from National Technical Information Service, Springfield, Virginia, Order No. PB 86-245286. We are proposing to incorporate that document by reference in the rule.

The use of physical stack height in excess of Good Engineering Practice (GEP) stack height is prohibited in the development of emission limitations under EPA's Air Program at 40 CFR 51.12 and 40 CFR 51.18. We propose to adopt a similar policy by limiting the height of the physical stack for which credit will be allowed in complying with the metals (and other) standards (i.e., both site-specific dispersion modeling and Screening Limits). GEP identifies the minimum stack height at which significant adverse aerodynamic effects are avoided. Although higher than GEP stack heights are not prohibited, credit will not be allowed for stack heights greater than GEP. Good Engineering Practice (GEP) maximum stack height means the greater of: (1) 65 meters, measured from the ground-level

elevation at the base of the stack; or (2) $Hg = H + 1.5L$.[60]

where:

Hg = GEP minimum stack height measured from the ground-level elevation at the base of the stack;

H = height of nearby structure(s) measured from the ground-level elevation at the base of the stack;

L = lesser dimension, height or projected width, of nearby structure(s).

If the result of the above equation is less than 65 meters, then the actual physical stack height, up to 65 meters, could be used for compliance purposes. If the result of the equation is greater than 65 meters, the physical stack height considered for compliance purposes cannot exceed that level.

EPA requests comment on this use of GEP maximum stack height. We note that although an owner or operator could increase his physical stack height up to the GEP maximum to achieve better dispersion and a higher allowable emission rate, he should first consider that EPA plans to develop for subsequent proposal in 1991 a best demonstrated technology (BDT) particulate standard that is likely to be much lower than the current 0.08 gr/dscf standard. Thus, it may be more cost-effective to upgrade emission control equipment to state-of-the-art control rather than increase stack height.

EPA specifically requests comments on how many facilities are likely to exceed the Screening Limits discussed below and, thus, would conduct site-specific dispersion modeling to comply with the proposed rule. Further, we request information on the changes to equipment and operations that would be required to comply with the Screening Limits if the provision for site-specific dispersion modeling was not available.

C. Screening Limits

EPA developed conservative Screening Limits for metals and HC1 emission rates (and feed rates) to minimize the need for site-specific dispersion modeling, and thus, reduce the burden on applicants and permitting officials.[61] The Screening Limits are

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[60] We note that this equation also identifies the GEP minimum stack height necessary to avoid building wake effects. EPA recommends the application of GEP to define minimum stack heights to minimize potentially high concentration of pollutants in the immediate vicinity of the unit.

[61] We note that the Screening Limits are designed to be conservative and would likely limit emissions by a factor of 2 to 20 times lower than would be allowed by site-specific dispersion modeling.

provided as a function of terrain-adjusted effective stack height, terrain, and urban/rural classification as discussed below. The Screening Limits would be included in the "Risk Assessment Guideline for Permitting Hazardous Waste Thermal Treatment Services" (RAG) which would be incorporated by reference in the rule.

1. *Emission Screening Limits.* As discussed in Section I of this Appendix, EPA derived conservative emissions Screening Limits by back-calculating from the reference air concentrations (RACs) and risk-specific doses (RSDs) using reasonable worst-case dispersion coefficients. The emission Screening Limits are presented in Tables E-5, E-6, E-7, and E-8, and E-10 in appendix E. Tables E-7 and E-8 apply to carcinogenic metals, and tables E-5 and E-6 apply to noncarcinogenic metals. Tables E-5 and E-7 apply to facilities located in noncomplex terrain. Different emissions limits are provided for urban versus rural land use because dispersion coefficients are significantly different for the land use categories. Tables E-6 and E-8 show emission limits for facilities located in complex terrain. No distinction is made for urban versus rural land use with complex terrain because of limitations in the available modeling techniques. If multiple carcinogenic metals are to be burned, (i.e., As, Cd, Cr, Be) then the following equation would be used to demonstrate that the aggregate risk to the MEI from all carcinogenic metals does not exceed 10^{-5} (the ratios must be summed because the screening limit for each metal is back-calculated from the 10^{-5} RSD for that metal).

$$\sum_{i=1}^{n} \frac{\text{Actual Emission Rate}_i}{\text{Emissions Screening Limit}_i} \leq 1.0$$

where:

n = number of carcinogenic metals

Actual Emission Rate = the emission rate in g/s measured during the trial burn or provided in lieu of the trial burn for metal "i"

Emissions Screening Limit = Limit provided in Table E-7 or E-8 in Appendix E for metal "i"

To demonstrate compliance with Emissions Screening Limits, the owner or operator would conduct emissions testing during the trial burn, as discussed below.

2. *Feed Rate Screening Limits.* Feed rate Screening Limits are provided to enable applicants burning wastes with

very low metals or chlorine concentrations to avoid emissions testing. The feed rate limits are "back-calculated" from the emissions Screening Limits assuming conservatively that all metals and chlorine in the waste are emitted to the atmosphere. Thus, no metals are assumed to partition to the bottom ash and no allowance is made for removal of metal or HC1 emissions by air pollution control devices. Consequently, the feed rate limits are equivalent to the emission limits, but are presented in units more consistent with waste feed rate, lb/hr, rather than g/s.

The Feed Rate Screening Limits are shown in Tables E–1, E–2, E–3, E–4 and E–9 in appendix E. Tables E–3 and E–4 apply to carcinogenic metals and Tables E–1 and E–2 apply to noncarcinogenic metals. Tables E–1 and E–3 apply to facilities located in noncomplex terrain. As with the emissions Screening Limits, different limits are provided for urban versus rural land use because dispersion coefficients usually are significantly different in urban and rural settings. Tables E–2, E–4, and E–9 show feed rate limits for facilities located in complex terrain. Again, no distinction is made for urban versus rural land use within complex terrain. These feed rates for carcinogen metals show the maximum quantity of any single metal that may be burned at any one time, in the absence of all others.

The feed rate limit for each carcinogenic metal ensures that ambient levels will not exceed the risk-specific dose at an incremental lifetime risk level of 1×10^{-5}. Similarly, the feed rates for the noncarcinogenic metals and HC1 ensure that the reference air concentrations (RACs) will not be exceeded. If the waste contains multiple-carcinogenic metals, then the following equation would be used to ensure that aggregate risk to the MEI does not exceed 1×10^{-5}.

$$\sum_{i=1}^{n} \frac{\text{Actual Feed Rate}_i}{\text{Feed Rate Screening Limit}_i} \leq 1.0$$

where:

n = number of carcinogens

Actual Feed Rate = the actual feed rate during the trial burn for metal "i" to be used in the permit

Feed Rate Screening Limit = limit provided in Table E–3 or E–4 in Appendix E for metal "i"

3. *Terrain-Adjusted Effective Stack Height.* For purposes of complying with the Screening Limits, terrain-adjusted effective stack height is determined by adding to the stack height the appropriate plume rise factor (which is a function of temperature and stack flow rate [62]) established in Table F–2 and by subtracting the maximum terrain rise within 5 km of the stack.[63] Since terrain has, however, already been taken into account in the dispersion modeling that supports the emission limits, this requirement effective "double counts" terrain effects. This additional conservatism is necessary to account for the wide range of terrain complexities encountered at real facilities—a range that could not be fully considered by modeling only 25 sites. If this double-counting leads to permit emission limits that the applicant considers unduly conservative, the applicant is free to conduct site-specific modeling.

TABLE F–2.—ESTIMATED PLUME RISE (H1, IN METERS) BASED ON STACK EXIT FLOW RATE AND GAS TEMPERATURE

Flow rate* (m3/sec)	Exhaust temperature (K)										
	<325	325–349	350–399	400–449	450–499	500–599	600–699	700–799	800–999	1000–1499	>1499
<0.5	0	0	0	1	1	1	1	1	1	1	1
0.5–0.9	1	1	1	1	1	1	2	2	2	3	2
1.0–1.9	1	1	1	2	2	2	3	3	3	4	4
2.0–2.9	1	1	2	3	4	4	5	5	6	6	7
3.0–3.9	2	2	3	4	5	6	7	7	8	8	9
4.0–4.9	2	2	3	5	6	7	8	9	10	10	11
5.0–7.4	3	3	4	6	7	8	10	11	11	12	13
7.5–9.9	3	4	5	8	10	11	13	14	15	17	18
10.0–12.4	4	5	7	10	12	14	16	18	19	21	23
12.5–14.9	5	5	8	12	14	16	19	21	22	24	27
15.0–19.9	6	6	9	13	16	19	22	24	26	28	31
20.0–24.9	7	8	11	17	20	23	27	30	32	35	38
25.0–29.9	8	9	13	20	24	27	32	35	38	41	44
30.0–34.9	9	10	15	22	27	31	37	40	42	45	49
35.0–39.9	10	12	17	25	31	35	41	44	46	50	54
40.0–49.9	11	13	19	28	34	39	44	48	50	54	58
50.0–59.9	14	15	22	33	40	44	50	55	57	61	66
60.0–69.9	16	18	26	38	45	50	56	61	64	68	74
>69.9	18	20	29	42	49	54	62	67	70	75	81

(1) Using the given stack exit flow rate and gas temperature, find the corresponding plume rise value from the above table.
(2) Add the physical stack height to the corresponding plume rise value to determine the effective stack height.
* Plume rise is a function of buoyancy and momentum which are in turn functions of flow rate not simply exit velocity. Flow Rate is defined as the inner cross-sectional area of the stack multiplied by the exit velocity of the stack gases.

As discussed above, the physical stack height component of the effective stack height, however, may not exceed good engineering practice for purposes of compliance. Note that increments in the categories are small when the terrain adjusted stack heights are low, and increase as the terrain adjusted stack height increases. This is because ambient concentrations are more strongly affected by variations in this

[62] Stack flow rate rather than flue gas velocity is the critical parameter because plume rise is a function of both buoyancy flux and momentum flux, both of which, in turn, are functions of flow rate. Flow rate is defined as the inner cross-sectional area of the stack multiplied by the exit velocity of the stack gases.

[63] We note that, in complex terrain where maximum terrain rise within 5 km of the stack exceeds stack height, the terrain adjusted effective stack height will be zero (or negative). Given that the Screening Limits applicable for a four meter terrain adjusted effective stack height have been calculated to be conservative for any stack height of four meters or less, the Screening Limits applicable for a four meter terrain adjusted effective stack height should be used.

term when stack heights are less than 30 meters.

The effective stack height is the height above the ground at which the plume becomes parallel to the ground after reaching equilibrium. Specifically, at the effective stack height the stack effluent has reached a final plume rise level and is assumed to remain at this height above the ground as it travels downwind. Therefore, the effective stack height is the physical stack height plus the final plume rise.

4. *Terrain Designation.* Terrain classifications are significant because dispersion of air pollutants is affected by the relationship between the maximum height of the surrounding terrain (especially within a radius of 1–2 km) and the effective height of the stack. EPA's analysis for this regulation reviewed three classes of terrain: flat, rolling, and complex. Although results for flat and for rolling terrain were sufficiently similar that these classes are combined for purposes of developing the Screening Limits (i.e., called noncomplex terrain), it will be necessary for applicants to determine whether their facility lies in noncomplex or complex terrain.

For purposes of applying the Screening Limits, a facility lies in noncomplex terrain if the maximum terrain rise within a radius of five kilometers of the stack is less than or equal to the physical stack height. If the terrain rise is greater than the physical stack height, the facility is in *complex terrain.*

5. *Land Use.* Characterization of urban versus rural land use is significant because pollutants tend to disperse differently in these two settings—rural areas tend to have a higher frequency of periods with limited dispersion. The "Guideline on Air Quality Models (Revised)" specifies a procedure to determine the character of the modeling area as primarily urban or rural. In this procedure, two methods are presented: (1) The land use procedure, and (2) population density procedure. The land use procedure is the recommended approach.

The land use procedure classifies land use within an area circumscribed by a 3 kilometer radius circle around a source. A typing scheme developed by August H. Auer, Jr. is referenced by the guideline as an aid in defining the specific types of land use. A simplified adaption of this procedure is recommended for this rule and is described in Tab A and Appendix I of the "Guidance on Metals and Hydrogen Chloride Controls for Hazardous Waste Incinerators".

D. Conservation of Risk Methodology

We specifically request comment on whether less conservative assumptions, coupled with a safety factor then applied to assure that ambient levels are not underestimated, should be used to develop the Screening Limits. This alternative approach may have merit because the repeated use of conservative assumptions in an analysis may "multiply" the conservatism unreasonably. Comments are solicited on: (1) The extent to which less conservative assumptions would enable applicants to meet the Limits and, thus, (2) how to reduce the conservatism of the Screening Limits while still ensuring that they are protective; and (3) how the reduced conservatism would affect the criteria discussed above that must be considered to determine if the Screening Limits are protective for a particular situation.

Appendix G: Implementation of Metals and HCl Controls

The metals emissions standards would be implemented by establishing limits in the permit on the feed rate (lb/hr) of each metal. If the applicant elects to comply with the feed rate Screening Limits, the Screening Limits for the noncarcinogenic metals would become the permitted levels. For carcinogenic metals, the permitted feed rate limits would be the feed rates the applicant uses to demonstrate that the sum of the ratios of actual feed rate to the Screening Limits for all carcinogenic metals does not exceed one.

If the applicant elects to comply with the emissions Screening Limits or to conduct site-specific dispersion modeling to demonstrate that higher emissions rates do not pose unacceptable health risk, metals emissions would be controlled in the permit by: (1) Limiting feed rates to those during the trial burn when metals emissions were determined; (2) limiting emission rates to those during the trial burn; (3) specifying key operating parameters that can affect metals emissions (e.g., maximum combustion chamber temperature, maximum chlorine content in the waste feed); and (4) specifying operating and maintenance requirements for the air pollution control device to ensure that collection efficiency does not degrade over time.

The waste feed rate limits (lb/hr) specified in the permit would represent maximum limits that can never be exceeded. We considered whether limits should represent average values (e.g., hourly, daily, weekly, monthly, or even yearly averages). We believe that

allowing (greater than hourly) averaging would complicate operator recordkeeping and EPA inspection and enforcement activities. EPA believes compliance with the standards can be enforced by sampling of waste feed inputs to the incinerator. EPA requests comment on whether and how alternate averaging periods should be allowed for compliance with the metals (and HCl) standards. It could be argued that long-term averaging is appropriate because the proposed acceptable ambient levels are based on long-term (annual) exposure. However, in selecting an averaging period, we must consider ease of enforcement and adverse health effects from short-term exposures to high ambient levels. One alternative approach would be to allow for the carcinogenic metals (i.e., arsenic, beryllium, cadmium, and chromium) and lead a 24-hour averaging period provided that emissions at any point in time do not exceed ten times the permit limit based on annual exposure. A ten-fold higher instantaneous ambient level for the carcinogenic metals may not pose adverse health effects given that the 24-hour average would not exceed the level that could pose a 10^{-5} health risk over a lifetime of exposure and that threshold (i.e., noncancer) health effects would not be likely at exposures only ten times higher than the 10^{-5} risk-specific dose. A ten-fold higher instantaneous ambient level for lead may not pose adverse health effects given that the proposed acceptable ambient level for long-term exposure to lead is based on only 10% of the National Ambient Air Quality Standard. We do not believe that a similar approach for the other noncarcinogenic metals would be appropriate given the uncertainty in the level of protection provided by the proposed long-term acceptable ambient levels (e.g., the ambient levels are based on oral RfDs converted 1-to-1 to inhalation values). We specifically request comment on this and other approaches to implementing the feed rate limits.

We also request comments on approaches other than waste analysis combined with feed rate limits to implement the controls on metals emissions. Other approaches that may be practicable include: (1) Determining the correlation between metals emissions and metals concentrations in emission control residues (e.g., scrubber water, bag house dust, ESP dust) during the trial burn followed by compliance monitoring of metals concentrations in the residues (e.g., daily analyses; daily composite sampling with weekly analyses; or daily composite sampling

with monthly analyses); (2) semicontinuous emission monitoring (e.g., 6 hours of every 24 hours of operation); and (3) ambient monitoring in conformance with procedures recommended by EPA's Office of Air Quality Planning and Standards.[64] Based on public comment and additional analysis, the final rule may provide one or more alternative approaches to waste analysis to implement the controls.

EPA believes that the metal in a waste may partition differently according to the type and location of the feed system through which a metal-bearing waste is fed. For example, the mass fraction of a metal in a solid waste fired onto the grate of a boiler and that subsequently enters the combustion gas stream and finally escapes the emissions control device and is emitted may be different from the mass fraction of a metal in a liquid waste fired with an atomization

nozzel that is ultimately emitted to the atmosphere. Similarly, wastes fired to cement kiln systems may partition differently depending on whether the waste is fired in liquid or solid form, and on firing location (e.g., hot end of the kiln, midkiln, precalciner). EPA anticipates, therefore, that separate feed rate limits may need to be set in the permit for each feed system. Consequently, permit applicants may wish to vary trial burn conditions to establish appropriate permit limits for metals fed through each separate feed system or location. EPA requests comment on the need for and practicality of such permit conditions.

EPA anticipates that boilers without air pollution control devices capable of capturing metals will choose to comply with the Feed Rate Screening Limits by controlling the levels of metals in the wastes and will blend higher levels of metals that exist in specific wastes

down to acceptable concentrations depending upon the capacity of the boiler.

For boilers and industrial furnaces equipped with air pollution control devices, we anticipate that the operator will comply with the Emissions Screening Limits. Compliance would be demonstrated by conducting an actual trial burn which measures metals emissions. Such operators will attempt in some instances to increase operating flexibility in their permits by ensuring that wastes of high metals contents are burned during trial burns. Spiking of metals in soluble forms may be advisable. Table G-3 gives typical conservative efficiencies for air pollution control devices on incinerators, and indicates the level of advantage operators may gain under Emissions Screening Limits (versus Feed Rate Screening Limits) by conducting emission testing.

TABLE G-3.—AIR POLLUTION CONTROL DEVICES (APCDs) AND THEIR CONSERVATIVELY ESTIMATED EFFICIENCIES FOR CONTROLLING TOXIC METALS

APCD	Pollutant				
	Ba, Be	Ag	Cr	As,Sb,Cd,Pb,Tl	Hg
WS [1]	50	50	50	40	30
VS-20 [1]	90	90	90	20	20
VS-60 [1]	98	98	98	40	40
ESP-1	95	95	95	80	0
ESP-2	97	97	97	85	0
ESP-4	99	99	99	90	0
WESP [1]	97	97	96	95	60
FF [1]	95	95	95	90	50
PS [1]	95	95	95	95	80
SD/FF; SD/C/FF	99	99	99	95	90
DS/FF	98	98	98	98	50
FF/WS [1]	95	95	95	90	50
ESP-1/WS; ESP-1/PS	96	96	96	90	80
ESP-4/WS' ESP-4/PS	99	99	99	95	85
VS-20/WS [1]	97	97	97	96	80
WS/IWS [2]	95	95	95	95	85
WESP/VS-20/IWS [1]	99	99	98	97	90
C/DS/ESP/FF; C/DS/C/ESP/FF	99	99	99	99	98
SD/C/ESP-1	99	99	98	95	85

[1] It is assumed that flue gases have been precooled in a quench. If gases are not cooled adequately, mercury recoveries will diminish, as will cadmium and arsenic to a lesser extent.

[2] An IWS is nearly always used with an upstream quench and packed horizontal scrubber.

C = Cyclone; WS = Wet Scrubber including: Sieve Tray Tower, Packed Tower, Bubble Cap Tower
PS = Proprietary Wet Scrubber Design (A number of proprietary wet scrubbers have come on the market in recent years that are highly efficient on both particulates and corrosive gases. Two such units are offered by Calvert Environmental Equipment Co. and by Hydro-Sonic Systems, Inc.).
VS-20 = Venturi Scrubber, ca. 20–30 in W. G. Δp
VS-60 = Venturi Scrubber, ca. > 60 in W. G. Δp
ESP-1 = Electrostatic Precipitator; 1 stage
ESP-2 = Electrostatic Precipitator; 2 stages
ESP-4 = Electrostatic Precipitator; 4 stages
IWS = Ionizing Wet Scrubber
DS = Dry Scrubber
FF = Fabric Filter (Baghouse)
SD = Spray Dryer (Wet/Dry Scrubber)

Finally, operators of facilities burning waste with high metals levels may elect to conduct site-specific dispersion

modeling to demonstrate that emission rates higher than allowed by the Screening Limits would not pose

unacceptable health risk. The added cost of the dispersion modeling may be reasonable even if the boiler or furnace

[64] Under the ambient monitoring approach, the Agency would consider increasing the RACs for the noncarcinogenic metals because exposure from

other sources would be accounted for. To consider indirect exposure, however, the RACs would still be based on a fraction of the RfD (e.g., 50% rather than

the 25% proposed). Further, the Agency may not raise the RAC for lead under this approach given that we now believe that lead is a probable human carcinogen.

is equipped with high efficiency emissions control equipment because the Screening Limits are likely to be conservative by a factor of 2 to 20.

Implementation for Multiple Sources On Site

The preceding discussion of the Screening Limits and Site-Specific Dispersion Modeling presumed only one hazardous waste combustion source at each site. However, facilities may have more than one source on site burning hazardous waste emitting from one or more stacks. EPA proposes that all such sources, whether incinerators, boilers, or industrial furnaces must meet the appropriate metals (and hydrogen chloride and THC) limits that would be established by this rule if such combustion devices burn hazardous waste. EPA anticipates that the revised incinerator standards that it plans to propose shortly would be copromulgated with the final rules for boilers and industrial furnaces. Thus, the sum of all emissions of toxic metals (and HCl and THC) from on-site sources must be considered when complying with the metals (and HCl and THC) standards.

EPA considered the method by which owners and operators could comply with this modified bubble approach. The net effect is to limit the total amount of metal-bearing waste at any one site with the use of adequate air pollution control devices. Thus, it would be inappropriate for the Agency to regulate metal emissions at an incinerator without taking into account the metal emissions generated by, for example, an on-site boiler burning hazardous waste and emitting toxic metals through the same or a nearby stack.

Owners and operators with multiple on-site sources could still demonstrate compliance with the Screening Limits by conservatively assuming all hazardous waste is fed to the source with the worst-case (i.e., considering dispersion) stack. The worst-case stack would be determined from the following equation as applied to each stack:

K=HVT
where:
K=a parameter accounting for relative influence of stack height and plume rise.
H=Physical Stack height (meters).
V=Flow rate (m³/second).
T=Exhaust temperature (Kelvin)

The stack with the lowest value of K is to be used as the worst-case stack.

The use of this assumption can be very conservative if there are substantial differences in effective stack heights. We assume that most facilities with multiple sources and stacks would perform site-specific dispersion

modeling to determine the relative importance of each source or stack contribution to the ambient metal (and HCl and THC) levels.

Short-Term Exposure Considerations for HCl

The dispersion modeling used to develop the Screening Limits indicated that, for the severe (i.e., poor) dispersion scenarios considered, the risk from short-term exposure was invariably greater than for long-term exposure. Thus, short-term (i.e., 3-min) exposures were used to develop the Screening Limits.

EPA proposed the 3-minute exposure RAC for HCl in the 1987 boiler/furnace proposal. Several commenters had concerns with the use of a 3-minute HCl RAC. Other commenters suggested alternative values for a short-term HCl RAC. We will consider those comments and other that may be submitted as a result of today's notice in developing the final rules.

EPA is evaluating continuous emission monitors for HCl, and it appears that accurate and reliable instruments may be available commercially. EPA specifically requests comments on whether continuous emission monitoring for HCl would be a feasible, practicable requirement in lieu of waste analysis for chlorine to limit HCl emissions.

Appendix H: Health Effects Data for Metals, HCl, and THC

A. Risk-Specific Dose for Carcinogenic Metals at 1×10^{-5} Risk Level

Constituent	Maximum annual average ground level concentration ($\mu g/m^3$)
Arsenic	2.3×10^{-3}
Beryllium	4.1×10^{-3}
Cadmium	5.5×10^{-3}
Chromium (hexavalent)	8.3×10^{-4}

B. Reference Air Concentrations (RACs) for Threshold Metals

Constituent	Maximum annual average ground level concentration ($\mu g/m^3$)
Antimony	0.3
Barium	50
Lead	0.09

Constituent	Maximum annual average ground level concentration ($\mu g/m^3$)
Mercury	0.3
Silver	3
Thallium (oxide)	0.3

C. Reference Air Concentrations for Hydrogen Chloride

Maximum 3-Minute Exposure—150 $\mu g/m^3$

Maximum Annual Average Ground Level Concentration—7 $\mu g/m^3$

D. Risk-Specific Dose (RSD) for Total Hydrocarbons at 10^{-5} Risk Level

Maximum Annual Average Ground Level Concentration—1 $\mu g/m^3$

Appendix I: Reference Air Concentrations (RACs) for Threshold Constituents

Constituent	CAS No.	RAC ($\mu g/m^3$)
Acetaldehyde	75-07-0	10
Acetonitrile	75-05-8	10
Acetophenone	98-86-2	100
Acrolein	107-02-8	20
Aldicarb	116-06-3	1
Aluminum Phosphide	20859-73-8	0.3
Allyl Alcohol	107-18-6	5
Antimony	7440-36-0	0.3
Barium	7440-39-3	50
Barium Cyanide	542-62-1	50
Bromomethane	74-83-9	0.8
Calcium Cyanide	592-01-8	30
Carbon Disulfide	75-15-0	200
Chloral	75-87-6	2
2-chloro-1,3-butadiene	126-99-8	3
Chromium III	16065-83-1	1000
Copper Cyanide	544-92-3	5
Cresols	1319-77-3	50
Cumene	98-82-8	1
Cyanide (free)	57-12-15	20
Cyanogen	460-19-5	30
Cyanogen Bromide	506-68-3	80
Di-n-butyl Phthalate	84-74-2	100
O-dichlorobenzene	95-50-1	10
P-dichlorobenzene	106-46-7	10
Dichlorodifluoromethane	75-71-8	200
2,4-dichlorophenol	120-83-2	3
Diethyl Phthalate	84-66-2	800
Dimethoate	60-51-5	0.8
2,4-dinitrophenol	51-28-5	2
Dinoseb	88-85-7	0.9
Diphenylamine	122-39-4	20
Endosulfan	115-29-7	0.05
Endrin	72-20-8	0.3
Fluorine	7782-41-4	50
Formic Acid	64-18-6	2000
Glycidaldehyde	765-34-4	0.3
Hexachlorocyclopenta-diene	77-47-4	5
Hexachlorophene	70-30-4	0.3
Hydrocyanic Acid	74-90-8	20
Hydrogen Chloride	7647-01-1	*15
Hydrogen Sulfide	7783-06-4	3
Isobutyl Alcohol	78-83-1	300
Lead	7439-92-1	0.09

Constituent	CAS No.	RAC (µg/m³)
Maleic anhydride	108-31-6	100
Mercury	7439-97-6	2
Methacrylonitrile	126-98-7	0.1
Methomyl	16752-77-5	20
Methoxychlor	72-43-5	50
Methyl Chlorocarbonate	79-22-1	1000
Methyl Ethyl Ketone	78-93-3	80
Methyl Parathion	298-00-0	0.3
Nickel Cyanide	557-19-7	20
Nitric Oxide	10102-43-9	100
Nitrobenzene	98-95-3	0.8
Pentachlorobenzene	608-93-5	0.8
Pentachlorophenol	87-86-5	30
Phenol	108-95-2	30
M-phenylenediamine	108-45-2	5
Phenylmercuric Acetate	62-38-4	0.075
Phosphine	7803-51-2	0.3
Phthalic Anhydride	85-44-9	2000
Potassium Cyanide	151-50-8	50
Potassium Silver Cyanide	506-61-6	200
Pyridine	110-86-1	1
Selenious Acid	7783-60-8	3
Selenourea	630-10-4	5
Silver	7440-22-4	3
Silver Cyanide	506-64-9	100
Sodium Cyanide	143-33-9	30
Strychnine	57-24-9	0.3
1,2,4,5-tetrachlorobenzene	95-94-3	0.3
2,3,4,6-tetrachlorophenol	58-90-2	30
Tetraethyl Lead	78-00-2	0.0001
Tetrahydrofuran	109-99-9	10
Thallic Oxide	1314-32-5	0.3
Thallium	7440-28-0	0.5
Thallium (I) Acetate	563-68-8	0.5
Thallium (i) Carbonate	6533-73-9	0.3
Thallium (I) Chloride	7791-12-0	0.3
Thallium (I) Nitrate	10102-45-1	0.5
Thallium Selenite	12039-52-0	0.5
Thallium (I) Sulfate	7446-18-6	0.075
Thiram	137-26-8	5
Toluene	108-88-3	300
1,2,4-trichlorobenzene	120-82-1	20
Trichloromonofluoromethane	75-69-4	300
2,4,5-trichlorophenol	95-95-4	100
Vanadium Pentoxide	1314-62-1	20
Warfarin	81-81-2	0.3
Xylenes	1330-20-7	80
Zinc Cyanide	557-21-1	50
Zinc Phosphide	1314-84-7	0.3

Appendix J: Unit Risks for Carcinogenic Constituents

Constituent	CAS No.	Unit risk (m³/µg)
Acrylamide	79-06-1	1.3E−03
Acrylonitrile	107-13-1	6.8E−05
Aldrin	309-00-2	4.9E−03
Aniline	62-53-3	7.4E−06
Arsenic	7440-38-2	4.3E−03
Benz(a)anthracene	56-55-3	8.9E−04
Benzene	71-43-2	8.3E−06
Benzidine	92-87-5	6.7E−02
Benzo(a)pyrene	50-32-8	3.3E−03
Beryllium	7440-41-7	2.4E−04
Bis(2-chloroethyl)ether	111-44-4	3.3E−04
Bis(chloromethyl)ether	542-88-1	6.2E−02
Bis(2-ethylhexyl)phthalate	117-81-7	2.4E−07
1,3-butadiene	106-99-0	2.8E−04
Cadmium	7440-43-9	1.8E−03
Carbon Tetrachloride	56-23-5	1.5E−05
Chlordane	57-74-9	3.7E−04
Chloroform	67-66-3	2.3E−05
Chloromethane	74-87-3	3.6E−06
Chloromethyl Methyl Ether	107-30-2	
Chromium VI	7440-47-3	1.2E−02
DDT	50-29-3	9.7E−05
Dibenz(a,h)anthracene	53-70-3	1.4E−02
1,2-dibromo-3-chloropropane	96-12-8	6.3E−03
1,2-dibromoethane	106-93-4	2.2E−04
1,1-dichloroethane	75-34-3	2.6E−05
1,2-dichloroethane	107-06-2	2.6E−05
1,1-dichloroethylene	75-35-4	5.0E−05
1,3-dichloropropene	542-75-6	3.5E−01
Dieldrin	60-57-1	4.6E−03
Diethylstilbestrol	56-53-1	1.4E−01
Dimethylnitrosamine	62-75-9	1.4E−02
2,4-dinitrotoluene	121-14-2	8.8E−05
1,2-diphenylhydrazine	122-66-7	2.2E−04
1,4-dioxane	123-91-1	1.4E−06
Epichlorohydrin	106-89-8	1.2E−06
Ethylene Oxide	75-21-8	1.0E−04
Ethylene Dibromide	106-93-4	2.2E−04
Formaldehyde	50-00-0	1.3E−05
Heptachlor	76-44-8	1.3E−03
Heptachlor Epoxide	1024-57-3	2.6E−03
Hexachlorobenzene	118-74-1	4.9E−04
Hexachlorobutadiene	87-68-3	2.0E−05

Constituent	CAS No.	Unit risk (m³/µg)
Alpha-hexachlorocyclohexane	319-84-6	1.8E−03
Beta-hexachlorocyclohexane	319-85-7	5.3E−04
Gamma-hexachlorocyclohexane	58-89-9	3.8E−04
Hexachlorocyclohexane, Technical		5.1E−04
Hexachlorodibenzo-p-dioxin (1,2 Mixture)		1.3E+00
Hexachloroethane	67-72-1	4.0E−06
Hydrazine	302-01-2	2.9E−03
Hydrazine Sulfate	302-01-2	2.9E−03
3-methylcholanthrene	56-49-5	2.7E−03
Methyl Hydrazine	60-34-4	3.1E−04
Methylene Chloride	75-09-2	4.1E−06
4,4'-methylene-bis-2-chloroaniline	101-14-4	4.7E−05
Nickel	7440-02-0	2.4E−04
Nickel Refinery Dust	7440-02-0	2.4E−04
Nickel Subsulfide	12035-72-2	4.8E−04
2-nitropropane	79-46-9	2.7E−02
N-nitroso-n-butylamine	924-16-3	1.6E−03
N-nitroso-n-methylurea	684-93-5	3.5E−01
N-nitrosodiethylamine	55-18-5	4.3E−02
N-nitrosopyrrolidine	930-55-2	6.1E−04
Pentachloronitrobenzene	82-68-8	7.3E−05
PCBs	1336-36-3	1.2E−03
Pronamide	23950-58-5	4.6E−06
Reserpine	50-55-5	3.0E−03
2,3,7,8-tetrachlorodibenzo-p-dioxin	1746-01-6	4.5E+01
1,1,2,2-tetrachloroethane	79-34-5	5.8E−05
Tetrachloroethylene	127-18-4	4.8E−07
Thiourea	62-56-6	5.5E−04
1,1,2-trichloroethane	79-00-5	1.6E−05
Trichloroethylene	79-01-6	1.3E−06
2,4,6-trichlorophenol	88-06-2	5.7E−06
Toxaphene	8001-35-2	3.2E−04
Vinyl Chloride	75-01-4	7.1E−06

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801
Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 86N-0479]

RIN 0905-AC54

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend its menstrual tampon labeling regulation to standardize each of the terms currently used to describe tampon absorbency, junior, regular, super, and super plus, so that each term represents a 3-gram range of absorbency. The rule requires that manufacturers describe absorbency using the term that corresponds to the absorbency of their tampons as determined by a test method specified in the final rule. The purpose of the final rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of all other brands and styles.

Labeling of tampons to allow consumers to compare the absorbency of different brands and styles is important because the use of tampons is associated with toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, and the risk of contracting TSS increases with the use of tampons of higher absorbency. FDA is issuing this rule under the Federal Food, Drug, and Cosmetic Act (the act).

FDA is also announcing its final response to a citizen petition submitted by the Public Citizen Health Research Group (HRG) concerning absorbency labeling for tampons.

EFFECTIVE DATES: The final rule is effective for packages of tampons initially introduced or initially delivered for introduction into commerce after March 1, 1990. In accordance with 5 U.S.C. 552(a), the Director of the Office of the Federal Register approves the incorporation by reference of the voluntary standard referred to in 21 CFR 801.430(f)(2); this approval is effective on March 1, 1990.

FOR FURTHER INFORMATION CONTACT: Les Weinstein, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 23, 1988 (53 FR 37250) (corrected November 3, 1988 (53 FR 44551, and January 17, 1989 (54 FR 1844)), FDA proposed to amend its current regulation governing user labeling for menstrual tampons (21 CFR 801.430) to require uniform absorbency testing of tampons and to standardize a method of expressing absorbency on tampon package labels. The agency proposed such testing and labeling requirements to enable consumers to make interbrand comparisons and choose the least absorbent tampon needed to control menstrual flow and, thus, reduce their risk of TSS.

Interested persons were given until December 22, 1988, to submit written comments on the proposal. The agency received more than 270 comments from tampon manufacturers, individual consumers, consumer groups, health care professionals, and researchers. After analyzing the comments concerning the agency's proposal to use a system of letters to represent absorbency ranges and not to standardize currently used terms of absorbency (e.g., regular, super, and super plus), the agency decided to issue a reproposal that would have replaced the letter designations with six absorbency terms that were different from, and would have been used in addition to, existing terms. The new terms (low absorbency, medium absorbency, medium-high absorbency, high absorbency, very high absorbency, and highest absorbency) corresponded to the six absorbency ranges described in the initital proposal (53 FR 37250). The reproposal, which was published in the Federal Register of June 12, 1989 (54 FR 25076) (corrected June 28, 1989 (54 FR 27188)), also would have required that the new terms be placed on the principal display panel of tampon packages to minimize any confusion that might have been created by the continued use of existing nonstandardized terms.

The reproposal included a summary of the comments received on the September 1988 proposed rule and the agency's response to them, and a tentative response to a citizen petition submitted by the Public Citizen Health Research Group concerning absorbency labeling for tampons. Interested persons were given until August 11, 1989, to submit written comments on the reproposal.

The agency received 39 comments on the reproposal from tampon manufacturers, individual consumers, consumer groups, and health care professionals. A summary of these comments and the agency's response to them are set out in section II of this preamble.

II. Summary and Analysis of Comments

A. General Comments

1. Almost all the comments, including those from tampon manufacturers, continued to support FDA's overall goal to ensure that absorbency information is provided to consumers. Specific suggestions included in the comments on how to improve the reproposed rule to provide the most truthful, accurate, and nonmisleading information on tampon absorbency are addressed in subsequent sections of this preamble.

FDA concludes, on the basis of the data and information discussed and cited, and for the reasons set out in the preamble to both the proposed rule and the reproposed rule and in this preamble, and taking into account the data, information, and views presented in the comments, that a final rule should be issued. As intended, the final rule will enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of all other brands and styles, to choose the lowest absorbency needed to control menstrual flow, and, as a result, to reduce their risk of TSS.

2. One comment addressed the proposed revision of the estimated incidence of TSS included in current 21 CFR 801.430(d)(2). This comment noted that much of the data on which FDA bases that estimate were published in 1980 and 1981, and that the composition of many tampons has changed since then. The comment recommended that FDA use only the most up-to-date published incidence rates (as cited in 54 FR 25076 at 25079, approximately 1 to 2 cases of TSS per 100,000 menstruating girls and women per year) and should disregard the earlier published data (as cited in the Federal Register of June 22, 1982 (47 FR 26982), between 6 and 17 cases of TSS per 100,000 menstruating girls and women per year).

As stated in the preamble to the reproposed rule (54 FR 25076 at 25079), FDA believes that the actual incidence of TSS can only be estimated, and that it is appropriate to convey to consumers the full range of reasonable estimates. There must be a rational basis for the agency to choose one estimate over another. FDA does not agree that the suggestion that the composition of many tampons has changed over the years provides such a basis. Therefore, FDA has concluded that the estimated incidence of TSS in current § 801.430(d)(2) should be revised as

proposed. The final rule states that estimate of TSS to be from 1 to 17 cases per 100,000 menstruating girls and women per year.

3. Two manufacturers commented on FDA's statement in the preamble to the reproposed rule (54 FR 25076 at 25079) that tampons are misbranded under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(f)(1)), because current tampon labeling does not contain any information with which a woman can determine relative absorbency of different brands of tampons. One manufacturer noted that FDA had attempted to clarify this issue, but recommended that, to avoid any possible confusion and misinterpretation of any final rule, FDA make clear that tampons on the market are not misbranded and that no tampon can be considered to be misbranded for noncompliance with the final rule unless it is introduced into commerce after the rule's effective date. The other manufacturer continued to disagree that the failure to provide such absorbency information renders tampons misbranded.

In response to these comments, FDA reiterates that, as the agency tentatively concluded (53 FR 37250 at 37254), omission of uniform absorbency information does render tampons misbranded within the meaning of section 502 (a) and (f)(1) of the act. But, rather than act against individual tampons to remedy the deficiency, FDA has elected, consistent with its authority, to address the misbranding by requiring a uniform labeling system through rulemaking. As provided in § 801.403(h) of the final rule, any tampon that is not labeled as required by the final rule and that is initially introduced into interstate commerce after the effective date of the final rule is misbranded under sections 201(n) and 502 (a) and (f) of the act (21 U.S.C. 321(n) and 352 (a) and (f)). (The effective date of the final rule is discussed in section II E of this preamble.)

B. Approaches to Absorbency Labeling

4. FDA specifically requested comment (54 FR 25076 at 25081) on whether the use of fixed, nonoverlapping ranges would be inconsistent with the goal of enabling consumers to reduce their risk of TSS. Comments on this issue were received from consumer groups, consumers, and tampon manufacturers.

One consumer group continued to reject fixed, nonoverlapping ranges stating that a single number is necessary to adequately convey absorbency information to consumers. This comment

suggested that the use of ranges would prevent women from being able to distinguish between tampon brands or styles at either the low or high end of a given absorbency range. It also noted that some styles of currently marketed tampons would have to be reformulated because their absorbency is on the boundary between ranges. The comment also urged that single numbers are more informative and clearer than ranges, that women are familiar with some manufacturers' current use of numbers, and that scientists have been using single numbers to designate the absorbency of tampons since 1981.

Most of the individual consumers favored the use of nonoverlapping ranges, as did three other consumer groups and all the manufacturers. These comments generally agreed with FDA's tentative conclusion (53 FR 37250 at 37260), or agreed with the statements on the issue in the reproposed rule (54 FR 25076 at 25080), that variations in tampon production and tampon absorbency testing make the use of ranges necessary; that the ranges chosen by FDA were appropriate and as narrow as possible given current production and testing; and that the benefit of truthful, nonmisleading, and accurate labeling outweighs the potential risks posed by the increased absorbency of some tampons that would result from product reformulation. Several individual consumers suggested reducing the number of ranges to avoid confusion and increase comprehension.

As stated in the preambles to the proposed rule (53 FR 37250 at 37260) and the reproposed rule (54 FR 25076 at 25080), the data show that a single numerical designation does not accurately represent the contents of a given box of tampons, and that the only truthful, accurate, and nonmisleading representation of the contents of a box can be that it contains tampons with absorbencies within a given range. Most of the comments agreed with FDA's interpretation of the data.

If future advances in technology across the industry allowed the production of tampons and the measurement of their absorbency such that there were only slight variations from an average absorbency, FDA would consider proposing amendments to this final rule.

Reducing the number of ranges could not be accomplished by simply eliminating one or more of them, because there is no basis for FDA to ban the use of any of the ranges, whether at the top or bottom end. The only way to reduce the number of ranges is to create ranges that are unnecessarily broad. FDA disagrees, therefore, with the

recommendation that the ranges of absorbency be reduced below six.

5. FDA received many comments on whether to standardize a new set of terms or standardize the existing terms currently used by manufacturers, e.g., regular, super, and super plus.

One manufacturer and six individual consumers supported the reproposal requiring the use of new and standardized terms, but allowing the use of familiar and unstandardized terms. The manufacturer argued that the reproposed absorbency nomenclature was straightforward and clear, and objected to standardizing existing terms because it would have little impact on reinforcing absorbency information.

Four consumer groups, 4 manufacturers, 1 health professional organization, and 15 individual consumers strongly objected to the reproposal to allow the dual use of a new set of standardized terms with nonstandardized existing terms. These comments were unanimous in their view that such a dual system would result in consumer confusion and the failure of the reproposed rule to accomplish its intended goal of enabling consumers to compare, before purchase, the absorbency of one brand and style of tampons with the absorbency of other brands and styles. These comments differed, however, in their suggestions on how to eliminate the confusion that would result from the labeling scheme in the reproposal.

One consumer group, the health professional organization, and nine individual consumers stated that the new terms in the reproposed rule were acceptable, and that confusion would be eliminated if the use of existing terms were proscribed. Three consumer groups, four manufacturers (representing approximately 90 percent of the tampon market), and six individual consumers argued that the best approach was simply to standardize the existing terms that have been used for years and with which women are familiar. In addition, several comments suggested minor modifications of the new terms, if the new terms were retained in the final rule.

FDA has concluded, based on its own analysis, and on the preponderance of comments, which represent a large portion of the public that will be affected by this rule, that allowing any combination of standardized and nonstandardized absorbency terms will confuse rather than inform consumers, as a result of which the reproposed rule would not have achieved its stated public health purposes. Presented with two sets of terms on the same package,

consumers would likely continue to choose tampons based on the familiar terms, which would not be uniform throughout the tampon industry.

The agency rejects the option of using the new terms in the reproposal and proscribing the use of existing terms because it would fail to take advantage of consumer familiarity with existing terms. Moreover, it would be a more restrictive limitation on labeling than is necessary to serve the purpose of the final rule.

The agency agrees with the suggestion simply to standardize existing terms, without the addition of any new terms for the following reasons. This approach avoids any possible confusion; it is likely to be very easily understood by all consumers; is overwhelmingly the option most favored by consumers, who are the target audience for the information; it is the simplest to implement; and it is strengthened by and takes advantage of consumer familiarity with existing terms. Accordingly, the agency has revised reproposed § 801.430(e)(1) in the final rule to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: less than 6, 6 to 9, 9 to 12, and 12 to 15 grams of fluid, respectively, and to provide for no absorbency terms for the two absorbency ranges above 15 grams of fluid. Because absorbency terms, for the first time, will be valid indicators of absorbency across all tampon brands and styles, FDA believes that it is appropriate to require the word "absorbency" to accompany the existing terms, just as the reproposal would have required the word "absorbency" to accompany the new terms. Also, requiring the word "absorbency" on the package in conjunction with the absorbency term will alert consumers to the fact that the labeling has been changed.

The final rule does not include a corresponding term of absorbency for the ranges 15 to 18 grams or above 18 grams of fluid. FDA is unaware of any currently marketed tampon that absorbs more than 18 grams of fluid and also is unaware of any currently used, and therefore familiar, term of absorbency used to describe such a product. Any person who is required to register under section 510 of the act (21 U.S.C. 360) and 21 CFR part 807 of FDA's regulation and who intends to begin the introduction or delivery for introduction into interstate commerce of such a tampon for commercial distribution is required to submit a premarket notification to FDA in accordance with section 510(k) of the

act and Subpart E of 21 CFR part 807 at least 90 days before making such introduction or delivery. Under § 807.87(e), a premarket notification for a device is to contain, among other things, labeling for the device. Based on such a submission for a tampon that absorbs more than 18 grams of fluid, the agency will determine whether the labeling is appropriate and does not misbrand or adulterate the tampon under section 501 or 502 of the act (21 U.S.C. 351 and 352) and whether the tampon requires premarket approval under section 515 of the act (21 U.S.C. 360e).

FDA is aware of one product in the 15 to 18-gram range that is currently labeled super plus. The manufacturer of this product will be required to lower the absorbency to continue to use the term super plus. All other manufacturers apply the term super plus to products with absorbencies in the 12 to 15-gram range. If the manufacturer using the term super plus for a product in the 15 to 18-gram range chose to keep this product at its current absorbency, FDA would review any term of absorbency proposed by the manufacturer. Because the final rule does not preclude the use of other labeling that is not false or misleading, the agency would consider the use of the absorbency range in § 801.430(e)(1) to be acceptable.

C. Absorbency Testing

6. Three manufacturers commented on the test method for determining tampon absorbency. One manufacturer recommended that the final rule permit manufacturers to use either the proposed or the reproposed method with appropriate technical adjustments that can be shown to be necessary to minimize error. Another manufacturer objected to the inclusion of a tensile strength requirement for the condom used in the test, arguing that there are no data showing that the results of the test are related to condom tensile strength and that ensuring that the tensile strength provision is met would be overly burdensome to tampon manufacturers. The third manufacturer objected to the provision in the reproposed rule that would have allowed alternative ways to reach the endpoint of the test (i.e., fluid either exits from the apparatus or appears in the folds of the condom below the tampon). The comment stated that this provision would create more interlaboratory error in the test method when some manufacturers select one alternative and some the other because, based on this manufacturer's preliminary data, the two endpoints

could vary by as much as 0.5 grams of fluid.

The agency continues to recognize that individual manufacturers may wish to use an absorbency test method different from the test method specified in the final rule. Therefore, the agency has retained in the final rule a provision for a manufacturer to submit evidence, in the form of a citizen petition, demonstrating to the agency's satisfaction that the alternative method will yield test results that are equivalent to the results using the test method in the final rule. FDA believes, however, that allowing "technical adjustments" to the test method by individual manufacturers would likely lead to significant differences between the absorbency results obtained by different manufacturers. Neither the proposed nor reproposed rules would have permitted such adjustments and FDA has included no provisions in the final rule for manufacturers to make technical adjustments without FDA approval as described above. The agency does agree, however, that multiple endpoints could result in unnecessary variability in test results between manufacturers. Therefore, in response to the comments, and after reconsideration of the position taken in the reproposed rule, § 801.430(f)(2) is revised to state that the test should be terminated when the tampon is saturated and the first drop of fluid exits the apparatus.

FDA disagrees with the comment objecting to the inclusion of a condom tensile strength provision. FDA included this provision in repsonse to a comment on the proposed rule indicating that there was a need to specify the condom to be used. The earlier comment included information that identifying one brand of condom would not suffice because modifications in that brand made by the condom manufacturer would affect the test result. As condom manufacturers modify their products to respond to the market desire for condoms that are more resistant to breakage, it is possible that unnecessary variations could be introduced into the test method. For these reasons, FDA has concluded that it is necessary to specify the tensile strength of the condom used in the test method. FDA does not believe that this requirement would be overly burdensome. FDA's experience shows that tensile strengths greater than 30 Mega Pascals are associated with clearly thicker latex condoms, suggesting that tampon manufacturers may be able to use thickness in acceptance testing to ensure this tensile strength requirement is met. Alternatively, quality assurance data

provided by the condom supplier could be available to the tampon manufacturer as a possible means to comply with this provision.

7. Three consumer groups continued to urge FDA to adopt a 95/95 tolerance interval to provide the highest degree of assurance that tampons in fact fall within the specified ranges. Three manufacturers agreed that a 90/90 tolerance interval was acceptable, but expressed concern over a wording change in the reproposal that would have applied the tolerance interval to tampons within a package and not within a brand and type.

As stated in the preamble to the reproposed rule (54 FR 25076 at 25084), FDA has concluded that it is technically infeasible for manufacturers to comply with a requirement that there be a 95 percent probability that 95 percent of tampons fall within the labeled range, that it is technically feasible for all manufacturers to comply with a 90/90 tolerance interval, and that a 90/90 tolerance interval would provide a sufficiently high degree of assurance that tampons fall within the labeled range. In the absence of data to the contrary, the agency has not changed its conclusion. FDA does agree that an inappropriate wording change was made in the reproposed rule when the tolerance interval was applied to tampons in a package. The intent of the agency remains as stated in the proposed rule where the tolerance interval was applied to tampons within a brand or type, and, accordingly, has revised the final rule.

8. One manufacturer continued to posit that imprecision in the test method warranted applying the tolerance intervals to average absorbencies from small groups of tampons. In support of this position, the manufacturer submitted additional data comparing the absorbencies of two groups of tampons with the same average weight. One group, however, had a normally distributed narrow weight range (± 1 percent) and one group had a normally distributed wide weight range (± 8 percent). The average standard deviation for the syngyna values of tampons from the narrow weight range group was 0.4, and the average standard deviation from the wide weight range group was 0.66. The comment interpreted these data as confirming that the variation was due only to the test method for the narrow weight range group and the test method plus weight variation for the wide weight range group. Because of the test method variability, the comment concluded that it was appropriate to allow averaging of

the absorbency values of small groups of tampons. Two consumer groups and one manufacturer agreed with FDA's conclusion that testing should be based on individual product unit values, rather than on averages.

FDA carefully evaluated the new data submitted in the comment and has concluded that the data do not demonstrate that there is such a large variability in the test method that it is necessary to apply tolerance intervals to average absorbencies. FDA believes that the data collection approach submitted with the comment, overlooks the contribution that all variables in the manufacturing process make to the final result. Thus, FDA concludes from the data that the standard deviation of 0.4 in the narrow weight group is the result of variations in the test method, fibers, and manufacturing; and that the standard deviation of 0.66 in the wide weight range group is the result of all of these variables plus weight. To find the variation attributable to the method exclusively would require a more detailed and carefully controlled experiment in which the several potential sources of variation in raw material and manufacturing were quantified and evaluated to determine their influence on the absorbency measurement.

D. Content and Location of Labeling

9. Four consumer groups and several individual consumers expressed concern that the use of the word "labeling" in reproposed § 801.430(d) would result in absorbency information being placed only in the package insert and not on the package label. One manufacturer suggested that the absorbency information be expanded to make specific reference to the link between tampon absorbency and the risk of TSS. Three consumer groups supported the language in the reproposal that would clearly identify in the labeling the practice of alternating tampon and sanitary pad use with reducing the risk of TSS.

The final rule (§ 801.430(e)(1)) requires that absorbency information shall be prominently and legibly placed on the package label of menstrual tampons. The absorbency information may not be placed only in a package insert. Section 801.430(e)(2) requires that the package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampon with the minimum absorbency needed to control

menstrual flow in order to reduce the risk of contracting TSS.

10. Three manufacturers expressed concern that the prominence requirement in reproposed § 801.430(e)(2) would result in restrictions on generic names, brand names, and the like that were not intended in the reproposal. One consumer group requested clarification as to the meaning of prominent and conspicuous in reproposed § 801.430(e)(2). To ensure prominence, various comments suggested graphs/ scales/guages; bold format, as in the Surgeon General's warning on cigarette packages; color-coding; and the use of dramatic labeling on cellophane wrappers.

Because FDA has decided in the final rule to require the standardization of existing terms instead of new terms, the language in reproposed § 801.430(e)(2) is removed from the final rule. Although FDA agrees that there are specific ways to ensure prominence of the labeling required in the final rule, the agency has concluded that there is no need to specify any single approach, thus providing flexibility to manufacturers.

11. Two consumer groups, two individual consumers, and one manufacturer commented on the need for ingredient labeling. The two consumer groups reiterated the support for ingredient labeling. The two individual consumers argued that it should not be necessary for an ingredient to be a health risk to justify ingredient labeling for tampons; materials should be disclosed so women can make an "intelligent choice," e.g., choose tampons with natural fibers. The manufacturer reiterated that manufacturers now voluntarily provide ingredient information, but agreed that FDA has insufficient legal basis for requiring it.

FDA tentatively concluded in the preamble to the reproposed rule (54 FR 25076 at 25085) that it does not have the authority under the act to require tampon manufacturers to list ingredient information on product labeling, unless such ingredient information were necessary for the safe and effective use of tampons. None of the comments favoring ingredient labeling cited, discussed, or submitted any data showing an association between any particular ingredient and any risk to health, including allergic reaction, sensitivity, or irritation, and FDA is unaware of any such data. Moreover, none of the comments provided any legal theory under which the agency could require ingredient labeling for tampons. Absent information indicating

that the disclosure of tampon ingredients on package labeling is necessary for the safe or effective use of the product, or that the omission of such information is material to the safe or effective use of the tampons, FDA has concluded that the act does not provide the agency with authority to require tampon manufacturers to list ingredient information on product labeling.

E. Effective Date

12. Two consumer groups supported a 6-month implementation date as the latest acceptable effective date. One manufacturer considered 6 months to be sufficient time for it to comply with the proposed rule. Three manufacturers continued to object to a 6-month effective date. These manufacturers claimed they would have difficulty meeting a 6-month effective date because they would have to make labeling changes and product design changes that would affect manufacturing, including machinery, and testing protocols. They also cited the unnecessary risk of having to scrap not only packaging but actual product in inventory. These comments suggested effective dates ranging from 9 months to 1 year. One individual consumer supported the view that 6 months was not enough time for manufacturers to design effective packaging to meet the new regulation.

As stated in the preamble to the reproposal, the agency believes that the basic testing methodology required by the final rule has been accepted by manufacturers, and that appropriate quality assurance programs have been in place since the device current good manufacturing practice (CGMP) regulations were promulgated in 1978 (21 CFR 820.20). Therefore, manufacturers are faced only with modification of existing quality assurance programs and not with creation of entirely new ones, and the need to develop and print new product labeling. Given the public health importance of tampon absorbency information, FDA believes that any time beyond 6 months is neither necessary nor appropriate for implementation of the provisions in § 801.430(e) (1) and (2), and (f) regarding absorbency ranges and testing. Based upon available information, FDA had proposed that any final rule become effective 6 months after the date the final rule is published in the **Federal Register**, because of the agency's belief that manufacturers would need this amount of time to implement the labeling changes required in § 801.430(e) (1) and (2). However, on September 29, 1989, the United States District Court for the District of Columbia ordered that the final tampon

absorbency regulation become effective 4 months after October 30, 1989, the date by which the court had, by its previous order of August 29, 1989, directed that publication of the final rule occur. *Public Citizen Health Research Group* v. *Commissioner, FDA*, Civil Action No. 88–1492. Accordingly, the final rule is effective on March 1, 1990. Any menstrual tampon that is not labeled as required by the final rule and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n) and 502 (a) and (f) of the act.

The agency believes that manufacturers might want for some period of time to relate new labeling to the former product labeling. Therefore, the agency would consider it appropriate if a manufacturer, for up to 12 months after the effective date of the final rule, chose to include, for example, the information "formerly Brand X super" in the product labeling.

F. Vending Machines

13. Two consumer groups and 10 individual consumers argued that the reproposed rule would not ensure that a consumer had the necessary information about absorbency of vending machine products in order to make an informed choice as between, for example, a tampon or a sanitary pad. One manufacturer argued that absorbency labeling of vending machine tampons is neither practical nor necessary, since consumers must purchase whatever single product is available in a particular vending machine and do not have a choice.

Because FDA has revised the final rule to standardize existing terms, the agency reviewed the provision (§ 801.430(g)) in the reproposed rule that did not exempt tampons sold in vending machines from the provision of § 801.430(e)(4). FDA no longer believes this provision is necessary, and has revised the final rule accordingly. FDA finds no basis in the comments for concluding that requiring tampons sold in vending machines to comply with the final rule is necessary to protect the public health.

G. Public Citizen Health Research Group Petition

14. No comments were received that specifically addressed the August 20, 1987, citizen petition from the Health Research Group (HRG) (see 53 FR 37250 at 37252 and 37253). FDA believes that the final rule, requiring uniform absorbency testing and a standardized method of expressing absorbency, is both technically feasible and adequate

to address the need for public health protection. The final rule enables women to compare absorbencies between brands and styles and to choose the lowest absorbency needed and, thus, reduce their risk of contracting TSS. To the extent that the final rule does not include provisions requested by HRG in its August 20, 1987, citizen petition, the agency is denying the petition.

H. Education

15. Three consumer groups and three individual consumers urged FDA to continue its public education efforts to inform users of the association between tampon absorbency and TSS risk. Specific suggestions included incorporating TSS education information into school curricula, using formats targeted to specific age groups and making public service announcements.

FDA agrees with the intent of these comments. FDA plans to employ a variety of educational approaches to provide updated information to new tampon users, higher risk groups for TSS such as young women and teenage girls, and the general public, and will consider the suggestions provided in the comments.

I. Miscellaneous

16. A comment from two consumer groups presented data on problems with the structural integrity of tampons and urged FDA to increase the priority for the development of a standard for tampon performance to include parameters such as biocompatibility, leachability of materials, anchor string strength, and smoothness and mechanical operation of the tampon inserter.

FDA will consider the new data submitted in the comment in its continuing revision of its priorities for development of mandatory standards for medical devices.

17. An individual consumer recommended against the use of metric measures, expressing the view that they are poorly understood and virtually meaningless to the general public.

The purpose of the determination of the fluid absorbed by a tampon is to provide a quantitative measure of absorbency that can be used in making interbrand comparisons. FDA does not believe that it is necessary to use English system units (ounces) to do that, and rejects the recommendation.

18. FDA also received suggestions for further changes in tampon labeling. For example, one comment recommended that the agency require

recommendations and warnings for women with unusually heavy menstrual periods. Another comment recommended establishing a minimum absorbency to protect consumers from fraudulent products and a maximum absorbency to safeguard the health of consumers.

FDA believes that the warnings about the link between TSS and tampon absorbency, and the admonition to reduce that risk by alternating tampon use with menstrual pads, will provide all women, including those with unusually heavy periods, the information they need to take action to reduce the risk of TSS. The agency does not believe that there is a basis for establishing either a minimum absorbency or a maximum absorbency for tampon products, and, therefore, rejects that comment.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

As stated in the preambles to the proposed and reproposed rules, FDA has assessed the economic consequences of the final rule in accordance with the criteria in section 1(b) of Executive Order 12291 and found that the rule is not a major rule under the Executive Order. No comments were received in response to the reproposed rule relating to FDA's assessment. As in the reproposed rule, FDA estimates that the final rule will impose direct costs of $75,000 on each tampon manufacturer. Therefore, the agency continues to conclude that the rule is not a major rule under the Executive Order. The agency also has considered the effect that the final rule will have on small entities including small businesses. The agency believes that only one of the affected manufacturers meets the definition of a small entity under the Regulatory Flexibility Act (Pub. L. 96-354), and no comments were submitted on the matter. Therefore, FDA certifies under the Regulatory Flexibility Act that the final rule will not have a significant economic impact on a substantial number of small entities. A further description of these new costs and the methods for estimating them can be found in the revised threshold assessment on file with the Dockets Management Branch, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

V. Paperwork Reduction

This final rule (§ 801.430 (e) and (f)) contains information collection requirements that were submitted for review and approval to the Director, Office of Management and Budget (OMB) as required by section 3507 of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910-0257.

List of Subjects in 21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.430 is amended by revising paragraph (b), the introductory text of paragraph (d), and paragraphs (d) (2), (3), and (4); by redesignating paragraphs (e) and (f) as paragraphs (g) and (h), respectively, and revising them; and by adding new paragraphs (e) and (f) to read follows:

§ 801.430 User labeling for menstrual tampons.

*   *   *   *   *

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

*   *   *   *   *

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

*   *   *   *   *

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

*   *   *   *   *

(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;

Ranges of absorbency in grams [1]	Corresponding term of absorbency
6 and under	Junior absorbency.
6 to 9	Regular absorbency.
9 to 12	Super absorbency.
12 to 15	Super plus absorbency.
15 to 18	None.
above 18	None.

[1] These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and

type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM), D 3492–83, "Standard Specification for Rubber Contraceptives (Condoms)"[1] for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber with a rubber band (see

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[1] Copies of the standard are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St., NW., Washington, DC.

Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27 ± 1 °C. The water returns to the waterbath as shown in Figure 2.

Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fuchsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.
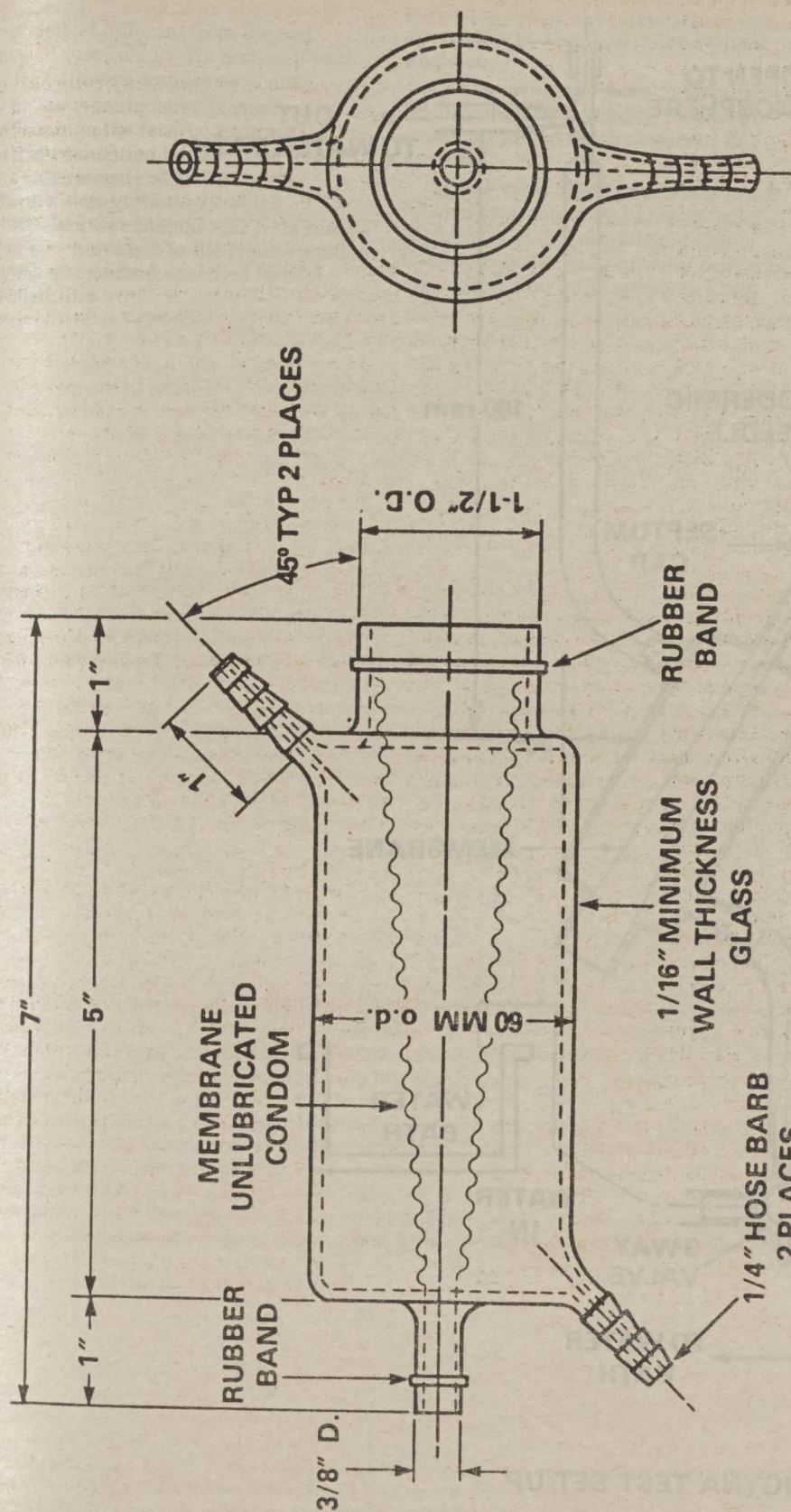
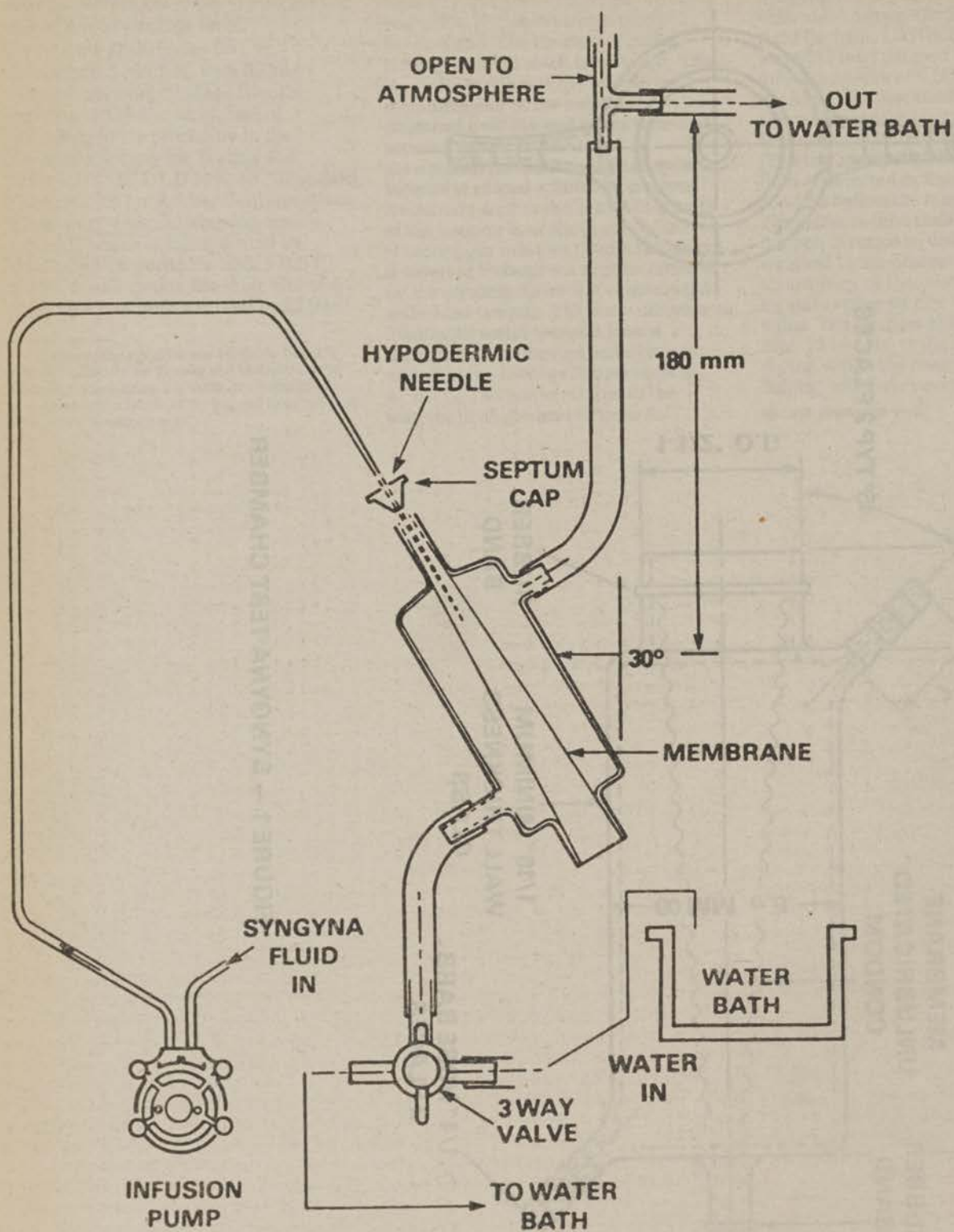BILLING CODE 4160-01-M

FIGURE 1 — SYNGYNA TEST CHAMBER

FIGURE 2—SYNGYNA TEST SET-UP

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified in this section if each of the following conditions is met:

(i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the **Federal Register.**

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after

March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910–0257)

Dated: October 17, 1989.

James S. Benson,

Acting Deputy Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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