EPA PROPOSED RULE FOR DEVELOPMENT AND IMPLEMENTATION OF RISK MANAGEMENT PROGRAMS FOR ACCIDENTAL CHEMICAL RELEASES [58 FR 54190, Oct. 20, 1993]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 68

[A-91-73; FRL-4790-1]

Risk Management Programs for Chemical Accidental Release Prevention

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: Under the Clean Air Act, as amended, the U.S. Environmental Protection Agency (EPA) is proposing regulations that would require development and implementation of risk management programs at facilities that manufacture, process, use, store, or otherwise handle regulated substances in quantities that exceed specified thresholds. EPA has proposed a list of regulated substances and thresholds separately. Risk management programs provide facilities with an integrated approach to identifying and managing the hazards posed by these regulated substances. The risk management plans developed under such programs would be registered with EPA, provided to the Chemical Safety and Hazard Investigation Board, state governments, and local planning authorities, and made available to the public. The proposed rule would assist facilities and communities in efforts to lessen the number and severity of serious chemical accidents.

DATES: Comments must be submitted on or before February 16, 1994. A public hearing will be held in Washington, DC, on November 30, 1993, from 9 a.m. to 5 p.m. Persons interested in appearing at a public hearing should register with EPA at (703) 218-2570 by November 23, 1993; a copy of the testimony should be submitted by November 23, 1993, to Dr. Lyse Helsing (see the FOR FURTHER INFORMATION section).

Docket: Supporting documentation used in developing this proposed rule is contained in Docket No. A-91-73. This docket is available for public inspection and copying between 8:30 a.m. and 12 noon, and between 1:30 and 3:30 p.m., Monday through Friday, at the address listed below. A reasonable fee may be charged for copying.

ADDRESSES: Comments may be mailed or submitted to: Environmental Protection Agency, Air Docket (LE-131), Attn: Docket No. A-91-73, Waterside Mall, 401 M St. SW., Washington, DC 20460. Comments must be submitted in duplicate. The public hearing will be held at Temple Micah, 600 M Street, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Lyse Helsing, Chemical Emergency Preparedness and Prevention Office, Environmental Protection Agency, OS-120, 401 M St. SW., Washington, DC 20460, (202) 260-6128; or the Emergency Planning and Community Right-to-Know Hotline, (800) 535-0202; in northern Virginia and Alaska, (703) 920-9877.

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Statutory Authority

This notice of proposed rulemaking (NPRM) is being issued under sections 112(r)(7) and 301(a)(1) of the Clean Air Act (CAA) as amended (42 U.S.C. 7412(r)(7) and 7601(a)(1)).

B. Background

Public awareness of the potential danger from accidental releases of hazardous chemicals has increased over the years as serious chemical accidents have occurred around the world (e.g., the 1974 explosion in Flixborough, England, and the 1976 release of dioxin in Seveso, Italy). Public concern intensified following the 1984 release of methyl isocyanate in Bhopal, India, that killed more than 2,000 people living near the facility. A subsequent release from a chemical facility in Institute, West Virginia, sent more than 100 people to the hospital and made Americans aware that such incidents can and do happen in the U.S.

In response to this public concern and the hazards that exist, the United States Environmental Protection Agency (EPA) began its Chemical Emergency Preparedness Program (CEPP) in 1985, as part of the Agency's Air Toxics Strategy. CEPP was a voluntary program to encourage state and local authorities to identify hazards in their areas and to plan for chemical emergency response actions. In 1986, Congress enacted many of the elements of CEPP in the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), also known as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). SARA Title III requires states to establish state and local emergency planning groups to develop chemical emergency response plans for each community. SARA Title III also requires facilities to provide information on the hazardous chemicals they have

on site to the states, local planners, and fire departments, and, through them, the public. This information forms the foundation of both the community emergency response plans and the public-industry dialogue on risks and risk reduction.

SARA Title III did not mandate that facilities establish accident prevention programs. However, Congress acknowledged the importance of accident prevention by requiring EPA, under SARA section 305(b), to conduct a review of emergency systems to monitor, detect, and prevent chemical accidents. The final report to Congress, Review of Emergency Systems (EPA, 1988), stated that

> * * * prevention does not depend on a single piece of equipment or a single technique. Prevention must be part of a comprehensive, integrated system that considers the hazards of the chemicals involved, the hazards of the process, the hazards to the community, and the capabilities of facility personnel. None of the elements should be considered in isolation nor should any single technical solution be considered a complete solution to a particular problem. Each change in a facility, process, or procedure will have multiple effects that must be assessed in the context of the entire operation.

The report concluded that the key to a successful process safety management system is the commitment of management (facility and corporate) to safety.

Although SARA Title III did not directly address accident prevention except through section 305(b), EPA recognized that prevention, preparedness, and response form a continuum. In 1986, therefore, EPA established a chemical accident prevention program to collect information on chemical accidents and to work with other groups to increase knowledge of prevention practices, encourage industry to improve safety at facilities, and foster increased awareness of prevention, preparedness, and response at the local level. Under this program, EPA developed its Accidental Release Information Program (ARIP) to collect data on the causes of chemical accidents and the steps facilities take to prevent recurrences. EPA also developed a program for conducting chemical safety audits at facilities to learn more about how facilities develop systems to prevent accidents. Through the audit program, EPA has trained its regional staff as well as state officials on how to conduct audits. EPA has worked with trade associations, professional organizations, labor, environmental groups, and other Federal agencies to determine how best to reach smaller operations, which the SARA section 305(b) study indicated are less facilities. EPA participant in international efforts related to chemical accident prevention, particularly through the Organisation for Economic Cooperation and Development, which has held five international workshops from 1989 through 1991 to discuss issues related to accident prevention, preparedness, and response, and has developed guidelines for member countries.

In addition to EPA's work in this area, other agencies, states, industries, trade associations, and professional organizations have developed programs related to chemical accident prevention. On February 24, 1992, the U.S. Occupational Safety and Health Administration (OSHA) promulgated a standard on chemical process safety management (57 FR 6356). Four states—New Jersey, California, Delaware, and Nevada—have regulations requiring facilities to prepare and implement risk management plans. The American Institute of Chemical Engineers (AIChE), through its Center for Chemical Process Safety, has published guidance on the management of chemical process safety as well as guidelines on topics related to hazard evaluation, vapor cloud dispersion modeling, handling and storage practices, and vapor cloud mitigation. The Chemical Manufacturers' Association (CMA) has adopted its Responsible Care™ program, with which all CMA members must comply to maintain membership. The American Petroleum Institute has developed a similar program (RP 750) for its members. In 1982, the European Community adopted the Seveso Directive (82/501/EEC, as amended), which requires facilities handling certain chemicals to develop a safety report that is similar to a risk management plan. Congress also recognized the need for a chemical accident prevention program at the Federal level and included prevention provisions in the Clean Air Act Amendments of 1990.

C. Clean Air Act Amendments of 1990

The Clean Air Act Amendments of 1990, signed into law on November 15, 1990, amend Clean Air Act (CAA) section 112 by adding a new subsection (r), which includes requirements related to chemical accident prevention. The goal of CAA section 112(r) is to prevent accidental releases of regulated substances and other extremely hazardous substances to the air and to minimize the consequences of releases by focusing preventive measures on those chemicals that pose the greatest risk.

Section 112(r) has a number of provisions. It establishes a general duty for facilities (i.e., stationary sources) to identify hazards that may result from releases, to design and maintain a safe facility, and to minimize the consequences of releases when they occur. Section 112(r)(3) requires EPA to promulgate a list of at least 100 substances that are known to cause, or may be reasonably anticipated to cause, death, injury, or serious adverse effects to human health or the environment when released to air. EPA is required to set thresholds for each listed substance. The proposed rule for the list and thresholds was published on January 19, 1993 (58 FR 5102). The proposed list includes 100 substances listed based on acute toxicity, 62 flammable gases and highly flammable liquids, and high explosives as a class.

CAA section 112(r)(7) requires EPA to promulgate, by November 15, 1993, "reasonable regulations and appropriate guidance" to provide for the prevention and detection of accidental releases and for responses to such releases. These regulations shall include, as appropriate, provisions concerning the use, operation, repair, and maintenance of equipment to monitor, detect, inspect, and control releases, including training of personnel in the use and maintenance of equipment or in the conduct of periodic inspections. The regulations shall require facilities to prepare and implement risk management plans that shall provide for compliance with regulations for managing risk (the "risk management program") and shall include a hazard assessment, a prevention program, and an emergency response program. The list and thresholds promulgated under CAA section 112(r)(3) will determine which facilities must comply with the accident prevention regulations.

The CAA, as amended, establishes a Chemical Safety and Hazard Investigation Board to investigate or cause to be investigated the causes of chemical accidents and to report its findings to Congress, Federal, state, and local authorities, and the public. Under the CAA, EPA is also required to conduct studies related to accidental releases, including research on hazard assessments, hydrogen fluoride, and air dispersion modeling.

In addition, section 304 of the Clean Air Act Amendments of 1990 requires OSHA to promulgate, under the Occupational Safety and Health Act (29 U.S.C. 655), a chemical process safety standard in order to protect employees from hazards associated with accidental releases of highly hazardous chemicals in the work place. OSHA promulgated its standard for process safety management for highly hazardous chemicals on February 24, 1992 (57 FR 6356). Sections IIC and IV of this

preamble discuss the relationship between EPA's proposed risk management program and the OSHA standard on chemical process safety management.

Finally, CAA section 112(l) requires EPA to develop guidance for states, especially for the registration of sources (facilities). This CAA section also contains the statutory authority for EPA to approve and delegate Federal authority to the states. For further information on EPA's proposed rule on CAA section 112(l), see 58 FR 29296, May 19, 1993.

II. Risk Management Programs

A. Clean Air Act Requirements

Today's proposed requirements to develop and implement a risk management program are in response to CAA section 112(r)(7)(B). Specifically, CAA section 112(r)(7)(B)(i) requires EPA to adopt "reasonable regulations and appropriate guidance" to provide for the prevention and detection of accidental releases and for response to such releases. As appropriate, the requirements shall address the use, operation, repair, replacement, and maintenance of equipment to monitor, detect, inspect, and control accidental releases, including the training of persons in the use and maintenance of equipment and in the conduct of periodic inspections. The regulations shall include procedures and measures for emergency response after an accidental release. The Act requires that the regulations be promulgated by November 15, 1993.

CAA section 112(r)(7)(B)(ii) states:

> The regulations under this subparagraph shall require the owner or operator of stationary sources at which a regulated substance is present in more than a threshold quantity to prepare and implement a risk management plan to detect and prevent or minimize accidental releases of such substances from the stationary source, and to provide a prompt emergency response to any such releases in order to protect human health and the environment.

The risk management plans must include a hazard assessment that evaluates potential effects of an accidental release of any regulated substance. The hazard assessment must include an estimate of potential release quantities and downwind effects, including potential exposure to populations. The assessment also must include a five-year release history, including the size, concentration, and duration of releases, and must consider worst-case release scenarios. The risk management plan must also document a prevention program including safety precautions, maintenance, monitoring, and employee training measures. The final specified element that must be documented in the risk management plan is an emergency response program that provides specific actions to be taken in response to a release to protect human health and the environment, including informing the public and local agencies, emergency health care, and employee training.

CAA section 112(r)(7)(B)(iii) requires that the risk management plans be registered with EPA. The plans must be submitted to the implementing agency, the Chemical Safety and Hazard Investigation Board, the state emergency response commission (SERC), and the local emergency planning committee (LEPC). These plans shall be available to the public under CAA section 114(c). EPA must establish a system for auditing the risk management programs. EPA must also ensure that plans are updated periodically.

The proposed rule would require facilities to do three things:

(1) Register with EPA three years after publication of the final rule in the **Federal Register**. The registration would consist of a written form to be sent to EPA headquarters indicating that the facility is covered by the rule, identifying the regulated substances triggering the registration and the quantity of those substances (in ranges) in a process. If the information on the registration changes (e.g., because new chemicals are added, chemicals are dropped, or the quantity changes), facilities would be required to submit an amended registration form;

(2) Develop and implement a risk management program that includes a hazard assessment, prevention program, and emergency response program, and maintain onsite documentation of the implementation. The hazard assessment would include offsite consequence analyses and a five-year accident history. The prevention program would consist of a process hazard analysis, process safety information, standard operating procedures (SOPs), training, maintenance, pre-startup reviews, management of change, safety audits, accident investigations, and a management system. The emergency response program would require emergency response plans, drills or exercises, and coordination with public emergency response plans; and

(3) Develop and submit to the Chemical Safety and Hazard Investigation Board, the implementing agency, SERC, and LEPC, a risk management plan (RMP) that would document the results of the risk management program including a summary of the offsite consequence analysis, a list of major hazards, steps being taken to address those hazards (i.e., a summary of the facility's prevention program), a five-year accident history, a description of the emergency response program, and a description of the management system that ensures the safety of the facility and the implementation of the required elements. This plan will be available to the public.

The risk management program addresses the general requirements of CAA section 112(r)(7)(B)(i) for regulations to provide for accidental release detection and prevention. The risk management plan, referred to as the RMP in this preamble, addresses the specific requirements of CAA section 112(r)(7)(B)(ii) for a plan that provides governmental entities and the public with information on the hazards found at facilities and the facilities' plans for addressing the hazards. These hazards would be identified and addressed through implementation of the risk management program elements. Therefore, the RMP would summarize the results of hazard assessments and analyses and the implementation of the risk management program requirements. The submission requirements (registration and the RMP) address the requirements of CAA section 112(r)(7)(B)(iii), as does the requirement for a system to audit RMPs.

B. Other CAA Provisions for Regulations

In addition to CAA section 112(r)(7)(B), CAA section 112(r)(7)(A) authorizes EPA to promulgate "release prevention, detection, and correction requirements which may include monitoring, record-keeping, reporting, training, vapor recovery, secondary containment, and other design, equipment, work practice, and operational requirements." EPA is investigating whether regulations, other than today's proposed rule on risk management programs, are necessary to prevent and detect accidental releases.

C. Relationship to OSHA's Process Safety Management Standard

The Clean Air Act Amendments of 1990 (CAAA) section 304 requires OSHA to promulgate a chemical process safety standard and a list of highly hazardous chemicals. To meet this mandate, OSHA promulgated its process safety management standard. The OSHA standard is intended to protect workers from chemical accidents at facilities using highly toxic, reactive, flammable, or explosive substances. EPA's mandate under section 112(r) of the CAA is to protect public health and the environment.

EPA and OSHA have met regularly to coordinate their rules to minimize conflicting requirements. To minimize confusion for facilities covered by both rules, the elements and language of EPA's proposed prevention program are, to the maximum extent possible,

identical to the parallel elements in OSHA's process safety management standard. The main differences between the EPA's proposed rule and OSHA's standard are those mandated by the CAA, such as the hazard assessment (offsite consequence analysis, the five-year accident history), the emergency response requirements, registration, and the RMP submission to the Board, implementing agency, SERC, and LEPC. In addition, for some elements of the two programs, OSHA's focus is on workplace impacts while EPA's focus is on offsite consequences, reflecting the differing statutory mandates of the two programs. The OSHA standard includes elements specific to worker issues that EPA has not included in its proposed rule. EPA anticipates that facilities in compliance with the requirements in the OSHA rule also will be in compliance with EPA's proposed prevention program elements. That is, for most prevention program elements, facilities that are in compliance with OSHA's process safety management standard will not need to do anything different or create different onsite documentation to comply with EPA's proposed prevention program requirements. Section IV of this preamble describes the differences that exist between the OSHA standard and EPA's proposed rule and outlines the correspondence between EPA's proposed rule elements and the OSHA standard.

Because EPA's proposed list of chemicals and thresholds and OSHA's list and thresholds are not identical (EPA covers more substances with acute toxic effects, fewer flammables and explosives, and no reactives) and because OSHA does not cover state and local government employees, the universes of facilities covered by the two rules are not identical, although they substantially overlap. See Section X of this preamble for a discussion of the universe of facilities covered by today's proposed rule.

III. Discussion of the Proposed Rule

A. Introduction

AIChE, in its *Technical Management of Chemical Process Safety*, says:

> Management systems for chemical process safety are comprehensive sets of policies, procedures, and practices designed to ensure that barriers to major incidents are in place, in use, and effective. The management systems serve to integrate process safety concepts into the ongoing activities of everyone involved in operations—from the chemical process operators to the chief executive officer. * * * Effective process safety management systems can, and do, vary a great deal in how they are implemented. However, they always address the need for managing the process safety-related aspects of technology, facilities, personnel, hazardous materials, and emergency responses.

The purpose of today's proposed rule is to require industry to develop such an integrated, holistic approach to managing the risks posed by the presence and use of regulated substances. EPA's proposed rule builds on process safety management elements included in OSHA's standard: process information, process hazard analysis, standard operating procedures, training, pre-startup reviews, mechanical integrity, management of change, accident investigation, safety audits, and emergency response. The implementation of these elements and the development of the RMP that will be submitted to governmental authorities will assist the owners and operators of facilities to identify hazards and construct a management system that addresses the hazards in a manner that is most effective for the specific circumstances and complexity of the facility.

EPA's proposed rule, particularly the prevention program, emphasizes the importance of management and management commitment for two reasons. First, without management commitment and an integrated system for managing process safety, it is unlikely that safety will be consistently recognized as a priority. Second, although for some facilities better or different technologies may be the most effective methods of addressing hazards, the technologies, by themselves, cannot ensure safety. Equipment must be maintained and workers trained in its proper uses. Changes in the process or procedures may affect the safe operation of technologies. Only with an integrated management system that continually evaluates the safety of a facility can the hazards posed by regulated substances be managed to minimize the likelihood of accidental releases.

Besides lessening the likelihood and severity of accidents, the implementation of process safety management can help facilities run more efficiently. Companies that have instituted risk management programs report reductions in injuries, lost-time accidents, mechanical breakdowns, maintenance costs, and material losses. Safety improvements will result in lower insurance costs. By preventing accidental releases, companies may minimize environmental damage and necessary cleanup costs. See Section X of this preamble for a discussion of the benefits of this rule.

B. Applicability

The CAA states that facilities covered by the risk management program regulations are those that have more than a threshold quantity of a regulated substance based on the final list and thresholds EPA will promulgate. In its list and threshold rule, EPA is proposing to exempt ammonia when used as an agricultural nutrient and held by a farmer. EPA requests comments on the proposed exemption and requests information on whether EPA should develop an accident prevention rule directed strictly to farmers using ammonia as a fertilizer. EPA notes that farm contractors who sell and apply ammonia as a fertilizer would be covered by today's proposed rule.

EPA estimates that approximately 140,425 facilities would be affected by today's proposed rule. Approximately 87,200 of those facilities would also be covered by OSHA's process safety management standard. The largest sectors covered by the rules would be cold storage facilities (which use ammonia as a refrigerant), public drinking water systems and publicly owned treatment works, manufacturers, and propane retailers. Some wholesalers and service industries would also be covered. See Section X of this preamble for a discussion of the estimated coverage and costs of this proposed rule.

The risk management program rules would affect only those areas at facilities where regulated substances are manufactured, processed, used, stored, or otherwise handled. If a facility uses a regulated substance in quantities above a threshold in only one process (e.g., wastewater treatment or refrigeration), only that process (as well as any unloading, transferring, and storing of the substance) would be covered by the rule. If a single process at a facility includes more than one regulated substance, a single process hazard analysis may cover all regulated substances for that process. EPA realizes that some facilities, such as batch processors (e.g., specialty chemical manufacturers), may have regulated substances on site for limited periods during the year; for example, a batch processor may use a regulated substance for only one month during the year. In some cases, these facilities may not be able to predict accurately which substances they will be handling. However, the Agency believes it is important for any facility that handles a regulated substance to have in place a program to manage risks and ensure safe operations. Because regulated substances would not be covered if they represent less than one percent by weight of a solution, EPA does not expect that the risk management program of publicly owned treatment works would need to cover the

substances they receive from facilities for treatment.

C. Definitions

A "significant accidental release" means any accidental release of a regulated substance that has caused or has the potential to cause offsite consequences such as death, injury, or adverse effects to human health or the environment or to cause the public to shelter in place or be evacuated to avoid such consequences.

"Worst-case release" would mean the loss of all of the regulated substance from the process in an accidental release that leads to the worst offsite consequences.

D. Risk Management Program Elements

The Clean Air Act mandates that the risk management plan document three elements: a hazard assessment, a prevention program, and an emergency response program. This section discusses the elements EPA is proposing for the risk management program to develop each of the plan requirements.

Hazard Assessment

As discussed above, the Clean Air Act requires a hazard assessment that includes evaluation of a range of releases including worst-case accidental releases; analyses of potential offsite consequences; and a five-year accident history. The language in the Conference Report suggests a more extensive assessment that would require a formal process hazard analysis (e.g., basic data on the source, identification of potential points of release, review of the efficacy of release and control measures). To allow EPA's prevention program requirements to parallel OSHA's process safety management standard, EPA is proposing to separate the offsite consequence analysis and five-year accident history from the formal process hazard analysis requirement. The proposed rule would require a hazard assessment that examines a range of accidental release scenarios, selects a worst-case accidental release scenario, analyzes offsite consequences for selected release scenarios including worst case, and documents a five-year history of significant accidental releases and accidental releases with the potential for offsite consequences. The other elements suggested in the Conference Report would be included under the prevention program in the process hazard analysis requirement.

EPA is proposing that facilities complete a hazard assessment for each regulated substance present above the threshold quantity. Facilities that use the regulated substance above its threshold in several locations or processes would need to evaluate a range of accidental releases and determine a worst-case release scenario for each location. The range of releases should include only those events that could lead to significant releases (i.e., accidental releases that have the potential to cause offsite death, injury, or serious adverse effects to human health or the environment). EPA requests comments on this issue.

EPA is proposing to define the worst-case release as the instantaneous loss of all of the regulated substance in a process, with failure of all mitigation systems (active and passive). EPA recognizes that this definition may require facilities to consider release scenarios that are highly unlikely. Such a definition will, however, define for the public the extreme worst-case. The proposed definition will also reduce the burden on regulated facilities; a requirement for analysis of a "credible worst-case" would lead to more analyses and documentation to defend the selected scenario. In addition, if each facility defined its own worst-case, local authorities could find it difficult to compare the results. EPA requests comments on the worst-case definition.

The Agency recognizes that this approach differs from the approach EPA used in its *Technical Guidance for Hazards Analysis* for local planners to assess credible worst-case releases for purposes of screening out situations with little or no impact. The credible worst case in the guidance assumed that the entire quantity of a substance was released from the largest vessel or group of interconnected vessels. Gases were assumed to be released in 10 minutes while liquids were assumed to be spilled on the ground or in a diked area and allowed to volatilize. Downwind impacts were assessed using conservative meteorological conditions. The Agency still supports this approach for screening, however, the methodology does not fully account for site-specific conditions that affect the rate of release. For example, gases may be stored in a liquefied state or a liquid may be handled in large quantities at higher than ambient temperatures giving much different release rates. The Agency believes that the worst-case analysis should account for site-specific conditions and physical chemical properties.

The Agency considered defining worst case as the instantaneous loss of the regulated substance from the largest containment vessel or pipeline on site. This approach is similar to the Technical Guidance approach. However, because the threshold quantity applies to the quantity in a process and the definition of a process defines the vessels and piping to be considered, the worst case should reflect the accidental release that could occur from catastrophic vessel and piping failures. The Agency requests comments on this approach.

In addition to the worst-case release scenarios, EPA would require facilities to analyze other more likely significant accidental release scenarios for each process in which the regulated substance is used above the threshold quantity. The proposed rule specifies several possible accident causes that facilities should consider when defining these more likely release scenarios. The list, however, should not be viewed as all inclusive. Each facility should examine its processes to determine the event or sequence of events that may lead to significant accidental releases. When examining these potential release scenarios, facilities would be allowed to assume that passive mitigation systems, such as containment dikes, functioned properly. Active mitigation systems, such as excess flow valves, fail-safe systems, scrubbers, flares, deluge systems, and water curtains, would be assumed to fail. EPA requests comments on this approach. The Agency plans to issue guidance on the evaluation of a range of accidental releases and determination of the worst-case scenario.

The proposed rule does not specify the number of other more likely significant accidental release scenarios facilities would be required to analyze. Although this approach provides flexibility, it may create uncertainty about what EPA will consider an adequate number of scenarios. EPA requests comments on whether it should specify a minimum number of scenarios to be analyzed, whether the minimum should vary with the complexity of the facility, and what the minimum(s) should be.

Once the worst-case and more likely significant accidental release scenarios are identified, the facility would be required to analyze the potential offsite consequences associated with these scenarios. The offsite analyses would estimate, using models or other approaches specific to each substance, the possible rate of release, quantity released, and duration of the release, and the distances in any direction that the substance could travel before it dispersed enough to no longer pose a hazard to the public health or environment. Facilities would be required to analyze the releases under average weather conditions for the facility and worst-case weather conditions, which would be defined as a wind speed of 1.5 meters per second and F stability (moderately stable weather conditions). For flammables

and explosives, the analyses should consider the distances in all directions that might be affected by pressure waves, fire, or debris. The analyses would also identify all populations that could be affected by such a release, including sensitive populations (e.g., schools, hospitals), and would detail potential environmental damage. EPA requests comments on the level of detail needed to define the population potentially exposed.

The fate and transport of the regulated substances can be evaluated using air dispersion models. EPA has published guidance on conducting similar analyses in its *Technical Guidance for Hazards Analysis*, much of which could be useful in developing the offsite consequence analyses. Computer models to estimate the impacts of vapor cloud explosions also are available. EPA, the Department of Transportation (DOT), and the Federal Emergency Management Agency have developed a model—the Automated Resources for Chemical Hazard Incident Evaluation (ARCHIE)—for vapor cloud explosion evaluation. The World Bank's WHAZAN model also evaluates this type of incident, as do other commercially available models. Simple equations can be used to calculate the impacts of explosions at various distances. EPA plans to develop additional guidance to assist facilities in analyzing offsite impacts.

Although the worst-case scenario is specifically defined, facilities are likely to use different models and approaches to estimate offsite impacts. In addition, facilities may need to use different models and analytical techniques to account for site-specific conditions in assessing offsite impacts associated with other scenarios. The Agency recognizes that facilities will need to have inhouse expertise or hire consultants with such expertise to complete these offsite impact analyses. This may pose a significant resource burden on some facilities, and the different approaches and models can make the offsite consequence results more difficult for local emergency planners to use. The Agency is working on ways to minimize this burden and make the results useful for local emergency planners. For example, the statute requires the Administrator to issue RMP guidance and model RMPs. The Agency is considering the development of a set of simple, generic tools that would be included in the guidance and that could be used for the assessment of offsite impacts. EPA could develop, for example, a generic methodology for assessing the offsite impacts similar to the methodology included in the *Technical Guidance for Hazards Analysis* cited above. Using a generic methodology for assessing the offsite impacts would allow a more direct comparison among facilities of potential offsite consequences. At the same time, this approach could reduce the resource burden imposed by the rule on many facilities, particularly smaller businesses by reducing the need for consultants to perform the offsite consequence analysis.

The Agency recognizes the limitations associated with simple, generic tools that will need to cover a potentially wide variety of scenarios. It would be difficult to construct a generic methodology which includes assumptions about the characteristics of chemicals, the range of chemical processes (e.g., conditions involving high temperatures and pressures), and other site-specific parameters. As a result, a generic methodology will generally be less sensitive to these conditions (or attributes) and may yield overly conservative or less realistic estimates of offsite impacts. The Agency requests comments on this approach and requests input on possible innovative ways to assist facilities in offsite impact analysis that might reduce the burden and provide meaningful, useful results.

Specific information on the worst-case scenario will help public emergency planners and responders recognize the maximum hazard potential surrounding the facility. The Agency recognizes, however, that the worst-case scenario may often be highly unlikely in comparison to other release scenarios with lesser potential consequences. Focusing on the worst-case scenario alone, therefore, could lead public agencies and the public to overestimate the threat posed by a facility. For this reason, EPA believes that facilities must examine a range of events in addition to the worst-case scenario and communicate information on these events to public agencies and the public to provide additional information on the hazards posed by the facility. In addition, EPA does not want facilities to focus solely on the worst-case release because other release scenarios are of concern, are generally far more likely than a worst-case release scenario, and must be addressed in the prevention program. Therefore, EPA is requiring facilities to analyze hazards associated not only with the worst-case scenario, but also with more likely significant releases.

EPA would require that facilities update the offsite consequence analyses every five years, with the RMP update, or sooner if changes at the facility or its surroundings might reasonably be expected to make the results inaccurate to a significant degree. For example, a substantial increase or decrease in the quantity of a regulated substance could significantly change the distance a substance could travel before dispersing and posing no hazard. Major changes in housing or land-use patterns, such as the construction of new, large-scale housing developments or commercial areas, could change substantially the population potentially affected.

A final element of the hazard assessment specified in the Act is a five-year history of releases of regulated substances. EPA interprets the accident history requirement to cover significant accidental releases and incidents that had the potential for offsite consequences because CAA section 112(r) is directed at preventing such releases. EPA is proposing to require the history to document releases that caused or had the potential to cause offsite consequences. As mandated by statute, the history must include the substance and quantity released, the concentration of the substance when released, and the duration of the release. EPA is also proposing that the date of the release, time of the release, and any offsite consequences (e.g., evacuations, injuries, environmental effects) be included. EPA believes that for releases of toxic substances, most of the releases that meet the criteria are already reported to the Federal or state governments under CERCLA and SARA Title III. Therefore, development of the five-year history of significant accidental releases would create little additional burden on facilities beyond maintaining records.

Prevention Program

The Act requires that the risk management plan include a prevention program that covers safety precautions and maintenance, monitoring, and employee training measures. Although the Act's requirements for the prevention program are general, a consensus exists among industry, professional organizations, labor, public interest groups, and government on what constitutes a good risk management program. In its *Review of Emergency Systems*, EPA listed elements of good management programs. The American Institute of Chemical Engineers (AIChE) has published *Guidelines for Technical Management of Chemical Process Safety*, which includes basically the same elements. Delaware, New Jersey, California, and Nevada have each adopted state risk management program regulations that again cover a similar set of elements. The OSHA chemical process safety management standard covers this same set of elements. Labor and environmental groups recommended similar requirements to

Congress and the agencies. Therefore, the prevention program EPA is proposing today consists of elements that the Federal government and several state agencies, as well as trade associations, professional organizations, labor, and public interest groups believe are necessary in order to have an integrated approach to understanding and managing risks associated with regulated substances at a facility. The elements of this integrated approach are consistent with and fulfill the requirements of the statute.

EPA is proposing a prevention program that adopts and builds on OSHA's process safety management standard and covers nine procedural areas: Process hazard analysis, process safety information, standard operating procedures (SOPs), training, maintenance, pre-startup review, management of change, safety audits, and accident investigation. The degree of complexity required for compliance for each element will depend on the complexity of the facility. For example, development of process safety information would take far more time and would require greater expertise at a large petrochemical facility than it would at a small drinking water system. As they develop plans for implementing the elements, facility owners or operators would have to consider the complexity of their chemical use, the hazards potentially posed by the chemicals, and potential consequences of an accidental release.

The prevention program elements must be integrated with each other on an ongoing basis. For example, each time a new substance is introduced to a process or new equipment is installed, the process hazard analysis must be reviewed, SOPs updated, training and maintenance programs revised, with new training if needed. An investigation of a near miss or a safety audit may reveal the need for revised operating and maintenance procedures, which will lead to revisions to SOPs, training, and maintenance. The investigation or audit may also indicate a need to review the process hazard analysis. The management system should ensure that a change in any single element leads to a review of other elements to identify any impacts caused by the change.

Management System

Because it is essential that all of the prevention program elements be integrated into a management system that is implemented on an ongoing basis, EPA is proposing that the owner or operator of the facility designate a single person or position to be responsible for the development and implementation of the overall program. At facilities where individual elements of the program are handled by different people or divisions, the names or positions of the people responsible for each element would also be specified and an organization chart or similar document required to define the lines of authority. At a small facility, a single person may be responsible for all elements. At a large company, separate divisions may handle emergency response, training, and maintenance; SOPs may be developed separately for each process area; safety audits may be conducted by corporate officials. In such a situation, it is essential that the involved divisions communicate with each other regularly so that the people in charge of training know when SOPs have been revised and that the emergency response personnel know when changes to processes may affect the hazards in a location. The purpose of the proposed management requirement is to have facility management define a system that integrates the implementation of the elements and assigns responsibility for that implementation.

Process Hazard Analysis

The AIChE's *Guidelines for Hazard Evaluation Procedures* (AIChE, 1985) defines a hazard evaluation (also known as a process hazard analysis) as a procedure intended "to identify the hazards that exist, the consequences that may occur as a result of the hazards, the likelihood that events may take place that would cause an accident with such a consequence, and the likelihood that safety systems, mitigating systems, and emergency alarms and evacuation plans would function properly and eliminate or reduce the consequences."

A process hazard analysis involves the application of a formal technique, such as a "What If" or a hazards and operability study (HAZOP). (AIChE's *Guidelines for Hazard Evaluation Procedures* provides descriptions of these techniques.) Formal techniques provide a method for a rigorous, step-by-step examination of processes, process equipment and controls, and procedures to identify each point at which a mishap may occur (e.g., a valve failing, a gauge malfunctioning, human error) and examine the possible consequences of that mishap, by itself and in combination with other possible mishaps. The result of a properly conducted process hazard analysis is a list of possible hazards of the process at the facility that could lead to a loss of containment and release of a regulated substance. Process hazard analyses must be conducted by people trained in the techniques and knowledgeable about the process and facility being examined. Such evaluations usually require at least two people, with other experts contributing to the process when necessary; a HAZOP may require a core team of five to seven people. For a simple process, the process hazard analysis may take a day or two; for complex processes, the evaluation may take six weeks to three months.

Although each prevention program requirement is important, EPA considers the process hazard analysis the critical element in developing a risk management program. When EPA analyzed the data collected for the *Review of Emergency Systems*, it was clear that a substantial number of respondents did not recognize the hazards associated with either the chemicals involved or the processes used. For the most commonly used, high-volume chemicals, such as ammonia and chlorine, a large number of facilities were relatively unaware of the hazards involved. A process hazard analysis would help facilities identify hazards and ways to address them. For example, a 1989 explosion and fire at a facility in Baton Rouge, Louisiana, led to a partial loss of pressure, power, and fire water because the power, steam, and water lines were co-located with the lines carrying flammable gases. The losses complicated and prolonged the process of responding to the release, thereby increasing the damage caused by the release. Similar problems occurred at a facility in Norco, Louisiana, where an explosion led to the loss of all utilities. A thorough and properly done process hazard analysis should identify these types of potential hazards and allow facilities to determine how to mitigate the problems. Process hazard analyses also identify situations where major accidents due to control failure (e.g., pressure gauges, overfill alarms) could be prevented by redundant or backup controls or by frequent maintenance and inspection practices.

Many other elements of a risk management program should flow from, or at least be revised based on, the results of the process hazard analysis. Existing standard operating procedures, training and maintenance programs, and pre-startup reviews may need to be revised to reflect changes in either practices or equipment that derive from the process hazard analysis. The process hazard analysis may help define critical equipment that requires preventive maintenance, inspection, and testing programs. It may also help a facility focus its emergency response programs on the most likely and most serious release scenarios. For many facilities, the process hazard analysis may be necessary to help define the worst-case release scenario that generates the worst

offsite consequences. A secondary benefit of the process hazard analysis is that it also can be used to identify pollution prevention opportunities. The same changes in procedures, equipment, controls, or chemicals that may lessen the likelihood of an accidental release often increase the efficiency of operations and result in waste minimization. These changes may reduce costs for facilities by improving the consistency and quality of products and by decreasing the amount of waste that needs to be treated.

The proposed rule would require facilities to conduct process hazard analyses after determining a priority order for the analyses based on the degree of hazard posed by the processes covered by the rule; that is, the facility would have to conduct its analyses on the most hazardous processes first, where the degree of hazard is related to potential offsite consequences, operating history of the process, and the age of the process. Facilities would be required to use one or more of six techniques: What If, Checklist, What If/Checklist, HAZOP, failure mode and effects analysis, or fault tree analysis. Facilities could also use an equivalent methodology provided the facility could demonstrate that the methodology is equivalent to the listed methods.

The complexity of the process hazard analysis procedure will depend on the complexity of the processes to which it is applied. Any of the listed techniques can be used for simple and complex processes although, for simple processes, the simpler procedures, such as the What If, may be more appropriate. Facilities such as wholesalers who load, unload, store, and sometimes repackage regulated substances would be able to use a simple technique such as a checklist to ensure that the substances are stored and handled properly and that fire suppression systems are appropriate for the substances at the facility. Application of the more complex procedures, such as the HAZOP or fault tree, requires considerable technical expertise and may be more appropriate for complex processes, such as those at petrochemical facilities. In some cases, facilities will want to use several techniques; for example, a facility might start with a What If analysis to identify high hazard areas, then use a HAZOP or fault tree method to examine those areas in greater detail. EPA is planning to develop guidance to help facilities select and use process hazard analysis techniques.

The process hazard analysis would require facilities to conduct a systematic examination of the process and procedures to identify ways in which equipment malfunction, human error, or external events could lead to an accidental release. The evaluation would also review the efficacy of prevention and control measures to prevent accidental releases. The team conducting the process hazard analysis would include at least one person knowledgeable in the technique and one knowledgeable in the process. EPA requests comments on whether the requirement for a person knowledgeable in the technique should be waived for facilities using checklists and what if questions from a model RMP. The team would be required to submit findings and recommendations to the owner or operator, who then would have to document all actions taken in response to the findings and recommendations, including schedules for implementing changes. In response to the CAA's requirement that the prevention program include monitoring, EPA is proposing that the owner or operator investigate and document a plan for (or a rationale for not) installing systems to detect, contain, or mitigate accidental releases if such systems are not already in place. Because accidental releases can be limited or mitigated by the use of detection, secondary containment, and mitigation systems, facilities should consider whether the hazards they have identified could be addressed through such systems. The decision on whether such systems are the best way to address the hazard must, however, rest, in the first instance, with the facility's management. In some cases, monitors and detectors do not exist; mitigation systems may not be technically feasible for certain types of releases. In other cases, steps such as improved procedures and maintenance may provide a more cost-effective approach to controlling the hazards. The purpose of the requirement is to ensure that facilities consider the available options and find the best method for the facility to address accidental releases.

As required by the CAA, the process hazard analysis must be reviewed and updated periodically. EPA is proposing that the process hazard analysis be reviewed and updated at least every five years, which is the same interval specified in the OSHA process safety management standard.

Process Safety Information

The process hazard analysis must be based on up-to-date chemical and process information, including information on physical and chemical hazards, process technology (e.g., process chemistry, process parameters), and equipment (e.g., equipment specifications and design, piping and instrumentation drawings). As per OSHA, after the effective date of the rule, facilities would also have to document material and energy balances for new equipment in a process that involve a regulated substance above the threshold quantity to ensure that the equipment is appropriately designed for the process. The material balance is intended only for ensuring the proper design basis for the equipment and is not useful for process inventory accounting or measurement of chemical loss. For example, it is necessary to know the flow rate in mass per unit-time to properly design a heat exchanger; however, this flow rate does not give the mass of the substance consumed or lost in a reaction system. All required process safety information would apply only to affected equipment, not the facility as a whole. Chemical information is available from Material Safety Data Sheets (MSDSs) mandated under OSHA's hazard communication standard (29 CFR 1910.1200). The level of process technology and equipment information would vary with the type of facility. For warehouses, wholesalers, and service industries, little equipment information would be needed unless special equipment is used with the regulated substances. For manufacturers, more extensive information would be required, including flow charts, piping and instrumentation diagrams of the facility as it currently exists, and electrical, relief, ventilation, and safety system specifications.

Standard Operating Procedures (SOPs)

The results of the process hazard analysis, information developed during the design of a process, and industry and facility experience combine to define the proper way to conduct operations and maintain equipment. SOPs describe the tasks to be performed by the operator, the operating parameters (e.g., temperature, pressure) that must be maintained, and safety precautions needed for both operations and maintenance activities. SOPs must specify the consequences of deviations from safe operating limits (e.g., if the safe operating temperatures are between 100 and 150°C, the SOPs should indicate what happens if the temperature is above or below those limits). Written SOPs provide a guide to safe operations in a form that can be used by employees. Lack of SOPs and inadequate SOPs have been implicated in a number of catastrophic accidents. For example, improper maintenance procedures have been blamed for a release and explosion at a facility in New Castle, Delaware, in 1980, which killed six people, injured 27 others, and caused more than $63 million in property damage to the facility.

SOPs, which define the proper steps to take in these emergency situations,

provide a quick source of information that can prevent or mitigate the effects of accidents. SOPs also provide workers and management a standard against which to assess performance; the procedures clarify for both operators and supervisors how operations should be carried out at the facility. Application of SOPs can result in more cost-effective operations by ensuring that operators adhere to procedures that maximize both the safety and efficiency of a process.

EPA is proposing that each facility develop written SOPs for each process and operation involving the regulated substance above the threshold. The SOPs would include instructions on steps for each operating phase (e.g., initial startup, normal operation, emergency shutdowns, normal shutdowns, emergency operations), operating limits, safety and health considerations, and safety systems. The facility would also be required to provide for control of hazards during operations involving lockout/tagout, confined space entry, and opening process equipment or lines. The facility would also need SOPs to control entrance to the facility by support personnel.

The level of detail included in the SOP should be appropriate for the operation covered. For example, instructions for proper storage of chemicals may be relatively brief, while procedures for routine startup of a complex process may require considerable detail to ensure that each action required is detailed and explained. EPA emphasizes that the SOPs should be useable by the operators in running the process; that is, the SOPs should be written in a language and at a level appropriate for the operators.

Training

Training provides employees with the information needed to understand what they must do to operate safely and why safe operations are necessary. The required training program is the key to ensuring the effectiveness of other program elements such as SOPs, maintenance programs, pre-startup reviews, and emergency response. Refresher training ensures that employees are reminded of appropriate procedures periodically. Training programs often provide immediate benefits to facilities because trained employees have fewer accidents, damage less equipment through mishandling, and conduct more efficient operations. Inadequately trained maintenance workers have been implicated in the 1989 disaster in Pasadena, Texas, which killed 23 people, injured 130 others, and destroyed $750 million of property at the facility. In 1988, at a plating facility in Auburn, Indiana, untrained workers used hydrochloric acid to clean a tank that had held zinc cyanide. The resulting hydrogen cyanide killed five workers and sent more than ten others to the hospital.

The proposed rule would require each owner or operator to train employees in applicable and appropriate SOPs and provide refresher training at least once every three years. Employers would also be required to ensure that each employee is competent to operate the process safely. EPA is not proposing specific standards for the training requirements because the Agency believes that each facility should have the flexibility to develop a training program that reflects its individual situation. Facilities that handle but do not process regulated substances (e.g., many facilities in the non-manufacturing sector) may provide relatively brief training because the procedures to be taught involve a few simple steps. For a complex manufacturing facility, training may take much longer for some operations. For some facilities, formal group training programs may be feasible; for small facilities, one-on-one training may be more appropriate. The form of the training program is less important than that relevant training is delivered in a manner most likely to be understood. Facilities would be required to document their training programs to indicate when employees were trained. EPA is also not proposing specific means of ensuring that the training is understood, such as testing, but would simply require that the owner or operator develop a system for ensuring competence and document that system. The proposed rule would require facilities to evaluate the effectiveness of the training and develop a schedule for reviewing and revising the training. EPA requests comments on this approach to training requirements.

Maintenance (Mechanical Integrity)

The Act specifies that the prevention program must include requirements for equipment maintenance. Preventive maintenance, inspection, and testing of equipment are critical to safe operations at a facility. Waiting for equipment to fail often means waiting until an accidental release occurs before addressing a problem. This approach is not acceptable, especially considering the extremely hazardous characteristics of the regulated substances. Preventive maintenance, inspection, and testing are needed because many of the potential failures are not obvious from visual inspections. For example, failed alarm systems or detectors may need to be tested to determine if they are functioning properly; detectors and monitors, which can provide early warnings of releases, must be calibrated periodically; corrosion of vessels and piping, a hazard with many chemicals, can be detected through testing well before the vessels or pipes fail; scheduled cleaning, oiling, or replacement of parts can prevent equipment failure. A large number of the accidents reported in the Marsh and McLennan review of the 100 largest losses in the petrochemical industry (Large Property Damage Losses in the Hydrocarbon-Chemical Industries, a Thirty-Year Review, 1990) were the result of equipment failure that might have been avoided through preventive maintenance. A 1978 fire and explosion at a Texas City, Texas, facility that led to almost $100 million in property damage was attributed to instrument failure and a faulty relief valve. A 1989 accident in Richmond, California, that injured workers and responders was caused by a failed weld.

Besides preventing accidental releases, maintenance programs also provide direct benefits to facilities by decreasing the amount of costly down-time that can result from failed equipment. Even in incidents where there is serious property damage, the lost business costs can be significantly greater than the property damage resulting directly from an accident.

EPA is proposing that facilities develop and implement a maintenance program, with written maintenance procedures and training for maintenance workers, for equipment and controls whose failure could lead to a significant accidental release. This equipment may include pressure vessels, storage tanks, piping systems, relief and venting systems, emergency shutdown systems, and controls such as monitors, alarms, sensors, and interlocks. Covered equipment should be inspected, tested, and subject to preventive maintenance. The intervals for such maintenance would depend on the equipment and how it is used. Manufacturers' recommendations may be used to set such schedules and determine testing procedures, but the applicability of those recommendations should be reviewed in light of industry and facility experience and the results of the process hazard analysis. In some cases, facilities will need to schedule more frequent inspections based on their specific uses or experience with equipment failure rates, or because the process hazard analysis indicated that

failure of a particular piece of equipment could result in a catastrophic loss of containment. Facilities would be required to replace or repair in a timely manner any equipment that is found to be outside acceptable limits. Facilities would also be required to develop procedures to ensure that replacement equipment and parts meet design specifications. Owners and operators would be required to document their maintenance program, including the written procedures, the schedules used, and the results of each inspection and test performed. The level of complexity and detail in the maintenance program would be directly related to the complexity of the operations and equipment.

Pre-Startup Review

Startup of a new or modified system can be a particularly hazardous time for facilities, especially for complex processes and those that require high temperatures, high pressures, or potentially exothermic reactions. However, even simple facilities need to conduct such reviews. For example, before a chemical distributor accepts a new regulated substance, the distributor should check that the fire suppression system is appropriate for the substance, that workers know how to handle and store the substance, and that emergency response procedures are in place to handle an accidental release.

To help ensure safety during startup, EPA is proposing that all critical systems be checked prior to startup of a new or substantially modified process. A new system would require a process hazard analysis prior to startup. A substantially modified process would include any process where the changes to the process are significant enough to require a reevaluation of the hazards involved because new hazards may have been created as a result of the changes. This review would include a list of items that operators would need to check or test before beginning an operation. Each pre-startup review should ensure that SOPs are in place and training has been conducted.

Management of Change

Chemical processes are integrated systems; changes in one part of the process can have unintended effects in other parts of the system. For example, installation of better seals may increase the pressure in vessels. It is, therefore, important that all changes in processes, chemicals, and procedures be reviewed prior to their implementation to identify any potential hazards that may be created by the modification. Although most changes at facilities are intended to improve safety and efficiency, any modification can have unintended effects and requires a specific review of the safety implications of the change. Other process modifications are instituted in response to a specific problem that arises unexpectedly. It was such an unexamined change in the installation of a temporary bypass at Flixborough, England, that led to the 1974 release and explosion that killed 28 employees, injured 89 people, and damaged almost 2,000 properties off site.

Therefore, EPA is proposing to require management of change procedures. These procedures are important for two reasons: (1) They help facilities evaluate changes and prevent accidents caused by unintended effects from alterations of equipment, procedures, and chemicals; and (2) they ensure that the process safety information and process hazard analyses are kept up-to-date. Under the proposed rule, the owner or operator of a facility would be required to evaluate every change in equipment (except changes that satisfy the design specifications of the device replaced), processes, chemicals, or procedures to ensure that the technical basis of the change is documented and that the change does not create new hazards; if new hazards are created or if the change results in different procedures being needed, these hazards and changes would need to be addressed prior to implementation. Training, SOPs, and maintenance programs may need to be revised as a result of changes; the process hazard analysis and hazard assessment may need to be revised as well.

Safety Audits

An important tool in ensuring that the process safety management elements are being implemented is the periodic safety audit. The safety audit provides management with a mechanism for oversight of the implementation of the safety elements and of the overall safety of the facility. Safety audits may take many different forms; some facilities use audits to check on compliance with specific regulations, some do spot-checks of safety practices, while others review all key aspects of safety management.

The proposed regulations would require facilities to conduct a complete safety audit once every three years to ensure that the process safety management elements are in place, updated, and being implemented properly. Although compliance with the proposed elements will provide an indication of safe operations, other considerations are important as well. For example, it is not enough to develop and train employees on standard operating procedures; the facility must check to see that procedures are being followed. Therefore, a safety audit is more than a review of regulatory compliance; it is a check, by management, that the facility is being operated safely. Facilities would be required to document their audits in a report that includes findings and recommendations. Management's response to the findings would also be documented. EPA chose the three-year interval to be consistent with the OSHA requirement for safety audits. EPA notes that for large facilities and those with a number of covered processes, the audit would not need to be performed at one time. The facility may choose to audit different processes on different schedules. The proposed rule would require only that over each three-year period, all covered processes are audited.

Accident Investigation

Accidents can provide valuable information about hazards and the steps needed to prevent accidental releases. Many times, the immediate cause of an accident is the result of a series of other problems that need to be addressed to prevent recurrences. For example, an operator's mistake may be the result of poor training, inappropriate SOPs, or poor design of control systems; equipment failure may result from improper maintenance, misuse of equipment (operating at too high a temperature), or use of incompatible materials. Without a thorough investigation, facilities may miss the opportunity to identify and solve the root problems.

Therefore, EPA is proposing that facilities investigate each significant accidental release. As discussed above, a significant accidental release is one that caused or had the potential to cause offsite death, injury, or serious adverse effects on human health and the environment. EPA notes that significant accidental release does not include near misses. EPA agrees with AIChE that "while it is important to investigate all incidents, as the lessons learned in preventing future incidents are not at all related to the magnitude of the occurrence, it is unquestionable that, at the very least, 'major incidents' should be investigated" (Guidelines for Technical Management of Chemical Process Safety). EPA encourages facilities to investigate all accidental releases, but would require only that significant accidental releases be investigated. EPA defines significant accidental release as "any accidental

release of a regulated substance that has caused or has the potential to cause offsite consequences such as death, injury, or adverse effects to human health or the environment or to cause the public to shelter-in-place or be evacuated to avoid such consequences." EPA requests comments on this approach to define the range of incidents requiring accident investigation. In particular, the Agency is interested in whether this definition covers too broad or too narrow a set of incidents, and requests comments on any alternative definition that provides greater regulatory certainty.

The accident investigation would determine, to the extent possible, the initiating event that led to the release, and the root cause(s); EPA emphasizes that identification of the root causes (e.g., misdesigned piping run) may be more important than identification of the initiating event (e.g., failed flange). The investigation would be summarized in a report to management; the report would include recommendations for steps that need to be taken to prevent recurrences (e.g., piping design review) and improve emergency response and mitigation measures. Management would be required to document its decisions on the recommendations. As with the management of change procedures, the degree of the accident investigation and documentation will vary with the potential seriousness of the accident. For example, a minor release that was prevented from becoming a major release only by prompt action of operators may require more investigation than a large release that can be quickly attributed to single failure (e.g., a faulty high-level alarm).

EPA is also concerned about near misses. Investigation of such incidents may provide facilities with important information on problems that should be addressed before a significant accidental release occurs. Information on near misses could help the Agency and facilities understand how accidents occur and how they can be prevented. EPA does not consider a release that occurred, but did not affect the public or the environment because of favorable weather conditions at the time of the release, a near miss. EPA considers this incident a significant accidental release and, therefore, it needs to be investigated. A near miss would refer to mishaps that did not result in a release for some reason other than explicit system design. For example, a release from a pressure relief valve that is vented to a scrubber would not be a near miss because the system is designed to ensure that relief valve releases are contained and treated. A near miss is a mishap that did not result in a release because of employee actions or luck. For example, a runaway reaction that is brought under control by operators is a near miss and should be investigated to determine why the problem occurred. EPA requests comments on whether facilities should be required to investigate near misses and on how near miss should be defined.

Emergency Response

CAA specifies that the emergency response program include actions to be taken to protect human health and the environment in response to a release, including informing the public and local agencies, emergency health care, and employee training. Emergency response procedures are a necessary part of a risk management program because accidents do happen even with the best safety systems in place. Emergency response procedures can reduce the severity of a release and protect employees, emergency responders, and the public from harmful exposure to the regulated substances. As discussed above, the damage from accidents and risks to responders can be increased if releases have the potential to damage or destroy utilities and equipment needed to respond to the incident. The emergency response plan helps define these worst cases and develop an approach to prevent potential problems.

EPA is proposing that each facility develop an emergency response plan that defines the steps the facility and each employee should take during an accidental release of a regulated substance. The plan would include both evacuation or protective action procedures for employees not directly involved in the response to the release, and the actions taken by employees responsible for responding to and mitigating the release. All employees would be trained in applicable emergency response procedures. The emergency response plan would include descriptions of all response and mitigation systems.

The emergency response plan would also include procedures for notifying the public of releases and of appropriate protective actions and procedures for notifying public agencies. The facility would be required to develop information on proper first-aid and emergency medical care necessary to treat accidental human exposure. EPA is also proposing that the facility emergency response plan be coordinated with the local emergency planning committee (LEPC) plans required under EPCRA for chemical releases. Upon request of the LEPC, the facility would be required to provide the LEPC with information necessary to develop and implement the LEPC plan. This requirement is a restatement of the mandate of EPCRA section 303(d)(3) and would be included in this rule to ensure that the facility and community planning efforts are coordinated, which will improve both plans, thereby facilitating effective response actions when releases occur. Facilities would be required to develop written procedures for the use of emergency response equipment and for its maintenance, inspection, and testing. Facilities would be required to conduct drills or exercises to test facility plans and revise the plans based on the results; facilities would be responsible for determining the number and type of drills or exercises they need to conduct and the frequency of these tests.

Most facilities are already required to have at least part of the emergency response plan in place. OSHA requires emergency action plans (29 CFR 1910.38(a)). Facilities that are subject to OSHA's and EPA's Hazardous Waste Operations and Emergency Response (HAZWOPER) rules (29 CFR 1910.120 and 40 CFR Part 311) also must conduct training for their facility response personnel. Facilities covered by EPA's RCRA regulations (40 CFR Parts 264 and 265) or by Spill Prevention Control and Countermeasure rules (40 CFR Part 112) also are required to have many of the emergency response elements in place. EPA requests comments on how the proposed requirements can be best integrated with these existing programs to minimize duplication.

E. RMP and Documentation

EPA is proposing that a risk management plan (RMP) be submitted to the implementing agency, Chemical Safety and Hazard Investigation Board, the SERC, and to the LEPC, and be made available to the public. EPA is proposing to make a distinction between the RMP that is submitted to these agencies (and through them to the public) and the documentation supporting the implementation of the risk management program elements that a facility would be required to maintain on site for inspection by EPA and other agencies.

The purpose of the RMP is two-fold: First, to provide government agencies and the public with sufficient information to understand the hazards at the facility and the approach the facility is using to manage the risks and, second, to have the facility develop an ongoing system for managing implementation of safety practices and procedures. The information provided

in the RMP will assist government agencies in assessing the quality and thoroughness of a facility's risk management program. Because of the large number of potentially affected facilities, it is unlikely that EPA or the state implementing agency will audit a substantial percentage of the facilities in any one year. Consequently, it is important that government agencies have enough information in the RMP to identify those facilities that pose the greatest potential hazards, either because of the quantity and kind of substances in use or because of prevention practices. The RMP information also will assist local emergency planners. Under SARA Title III, local planners have received information on substances and quantities at facilities. The RMP will add to these data by providing information on hazards and practices. For example, a large facility with a well-implemented risk management system may pose less of a hazard than smaller facilities, with smaller quantities of chemicals, that have weak programs. With this information, local planners will be better able to focus on facilities that pose the greatest risk and target their work with facilities to improve prevention practices. The public will be able to identify hazards and risk management procedures from the RMP without having important information obscured by detailed submissions.

The second purpose of the RMP is to assist facilities in integrating the risk management program elements. Each facility will approach the management of its hazards in a way that is appropriate for its specific situation. For small facilities, one person may be responsible for implementing and integrating the elements. In large corporations, many of the elements may be handled by different operating divisions. The RMP would include information on the management system the facility uses to integrate the elements and ensure responsibility for the program. EPA thinks that this is an essential step in successful implementation of the program because unless management is accountable for safety and makes it a priority, other employees may not consider safety important. Equally important, by reporting on how it is addressing each of its major hazards, the facility would have to explain how it has applied the various risk management program elements to prevent accidental releases.

The proposed rule would require facilities to submit an RMP that includes the following information:

- A copy of the registration form;
- A summary of the offsite consequence analyses including worst-case and other more likely release scenarios;
- The five-year history of significant accidental releases for each regulated substance;
- A list of the major hazards defined through the process hazard analysis, the consequences of failure to control each major hazard, the steps management is taking or planning to take to address the hazards, and an implementation schedule for each step listed;
- A summary of any risk management program elements not covered under the steps taken to address specific hazards (e.g., if training has not been revised to respond to any listed hazard, a summary of the training program would be needed);
- A summary of the facility's emergency response program, including dates and schedules for drills completed and planned, information on coordination with the public, procedures for notifying and alerting the public of a release, and the name of person responsible for coordinating with public agencies;
- A description of the management system used to implement and integrate the elements of the hazard assessment, prevention program, and emergency response program; and
- A certification of the accuracy and completeness of the information.

EPA envisions the RMP to be comprehensive and succinct. The offsite consequence analysis information should be a summary of the documentation already developed during the hazard assessment. To keep the size of the RMP manageable, EPA requests comments on whether it should specify a maximum number of release scenarios a facility may submit as part of its offsite consequence analyses. Complex facilities may conduct a substantial number of such scenarios; submission of every scenario analyzed could overwhelm the user and make the information less useful.

The accident histories can be presented as tables or lists. EPA is not proposing that facilities include every hazard identified through a process hazard analysis, but rather that the RMP include only those hazards that have the potential to lead to significant accidental releases with offsite consequences. For each item included in the RMP, the documentation required by the rule would serve as supporting information.

The information provided should be brief. For example, if corrosion in piping is a hazard, the facility would list corrosion in piping followed by any steps taken to control corrosion and to ensure that corroded pipes are replaced before a release occurs. These steps might include periodic ultrasonic testing, replacement of pipes, or something similar. For facilities where the steps taken to address hazards apply to several hazards, the hazards can be grouped under the steps. For example, if revised operating procedures and training were used to control and prevent a number of hazards, the facility could list operating procedures and training followed by the hazards to which they apply. In this way, duplicative entries can be minimized. The length of the list of hazards would vary with the complexity of the facility and with the current state of prevention practices.

EPA is proposing an RMP that summarizes the program because the Agency believes that the information of most use to the public and local agencies will be related to the hazard assessment and consequence analysis, as well as general descriptions of hazards at the facility. Other detailed information is likely to be of little interest and, if submitted, could overwhelm the ability of local agencies to manage and use the information. EPA also believes that the RMPs should not include information that facilities can legitimately claim as confidential business information under CAA section 114(c). The RMP should provide local and state agencies and the public with sufficient information to determine if additional information is needed. The information will be available, if needed, to EPA or state officials conducting audits or compliance inspections. EPA requests comments on the RMP and particularly on the information communities, local authorities, and public interest groups will find useful in assessing the hazards posed by facilities. EPA also requests comments on the kinds of information facilities consider confidential (and how facilities can report on hazards without revealing confidential data).

EPA is proposing that the RMP shall be submitted to the Chemical Safety and Hazard Investigation Board, to the implementing agency, the state, and to local emergency planning committees. EPA asks for comments on other local agencies that may want a copy of the RMP. EPA is concerned about the burden such submissions may place on the entities receiving the RMPs. If each RMP is submitted, the Board could receive more than 140,000 plans; some states could receive several thousand documents. At the local level, the number could vary from a few to more than 50 plans.

EPA is considering three options that might lessen the burden. First, EPA could develop computer software that would provide facilities with standard formats for completing the information required in the RMP. The RMP could then be submitted on disk in a format that would allow the government agency to locate information quickly. EPA recognizes that while this approach might ease storage problems and related burdens for the Board and the states, many local entities are not equipped to receive documents on disk. In addition, many of the smaller facilities covered by the rule may not yet be computerized. Therefore, this approach would work for only part of the facilities and recipients. The second option would be to allow local authorities to designate the state as the receiving entity, thereby lessening the burden on the local authorities. The third approach would be to require that the RMP be submitted only on request from the Board, state, or local entity. Facilities would be required to develop the RMP and keep a copy available on site, but would submit it only if requested. EPA solicits comments on these approaches and specifically asks for suggestions on other ways EPA might be able to facilitate the management and use of the RMP information by state and local agencies.

Section 112(r)(7)(B)(iii) requires EPA to establish, by rule, a system for auditing RMPs and requiring revisions where necessary. EPA is proposing that facilities be selected for audits based on a number of criteria. Specific accidents at a facility or the facility's five-year history of accidents would be one criterion used to select a facility for an audit; similarly, if other facilities in the same industry show a pattern of accidents with regulated substances, a facility might be selected for an audit to ensure that it is addressing the kinds of hazards causing releases at similar facilities. The quantities of regulated substances or the presence of specific regulated substances would also be criteria. For example, facilities with high volumes of one or more regulated substance might be selected, or the audits might focus on particular substances. The location of the facility would be a criterion for selection; facilities close to populated areas, or sensitive populations or ecosystems might be audited because of the potential hazard they pose. The hazards identified in the RMP would be a criterion for selection. Finally, facilities might be randomly selected to provide neutral oversight. EPA requests comments on the proposed criteria. EPA also requests comments on whether major facilities should be audited on a regular schedule (e.g., every three to five years).

The audit is designed to cover the adequacy of the RMP. If, based on the audit, the implementing agency decides that revisions to the RMP are needed, the agency would issue a preliminary determination explaining the basis for the revision and a timetable. This preliminary determination shall include an explanation for the basis for the revisions, reflecting industry standards and guidelines (such as AIChE/CCPS guidelines and ASME and API standards) to the extent that such standards and guidelines are applicable, and shall include a timetable for their implementation. The owner or operator would have 90 days to respond to the preliminary determination in writing, either agreeing to implement the changes or rejecting the revisions, in whole or in part, with an explanation for any rejection. In its response, the owner or operator may develop substitute revisions addressing the same issues addressed in the preliminary determination. After providing the owner or operator an opportunity to respond, the agency would issue a final determination, which may adopt or modify proposed revisions, or may adopt substitute revisions proposed by the facility. A final determination that rejects a substitute revision would explain the reason for the rejection. Thirty days after the final determination, the facility would be considered to be in violation of the rule unless the RMP is revised. The public would be assured access to preliminary determinations, responses, and final determinations.

In addition to the RMP, the facility would be required to maintain onsite documentation of its process hazard analysis, offsite consequence analysis, process information (e.g., P&IDs, MSDSs), training and maintenance programs, SOPs, pre-startup review list, management of change procedures and records, compliance audits, accident investigation procedures and reports, and emergency response plans. This documentation would include schedules for starting and completing actions based on the recommendations of the process hazard analysis, safety audit, and accident investigation. These documentation requirements are similar to those imposed under OSHA's standard.

F. Registration

Information Required

The Act requires that RMPs be registered with EPA prior to the effective date of the regulation. EPA is proposing that, within three years of the date of publication of the final rule, all facilities register with EPA if they have a regulated substance in a quantity that exceeds the threshold quantity. EPA is proposing a simple registration that would require most facilities to complete a one-page form; facilities with large numbers of regulated substances may need an additional page to list the substances. The registration would ask for the name and address of the facility, the facility's Dun and Bradstreet number, the regulated substances on site, quantities of the substances (in ranges), and the facility's Standard Industrial Classification (SIC) code(s) that apply to the use of each substance. If, at any time after the registration is submitted, the information becomes inaccurate, the facility would be required to file an amended registration within 60 days with the Administrator and the implementing agency.

The association of SIC codes with specific substances would allow EPA to identify the types of processes in which a facility may use the substance without requiring the facility to provide detailed information during registration. The Dun and Bradstreet number is a common identifier for facilities and would allow EPA to cross-reference the data with other EPA databases. Most of the information requested is already reported under SARA Title III. The reporting ranges proposed are the same ranges used for SARA Title III reporting.

EPA is proposing a registration requirement for several reasons. First, the statute requires that RMPs be registered with EPA. Second, EPA is required to establish a system for auditing RMPs. To implement an auditing system, EPA and state agencies that implement the program need to know which facilities are covered by the rule as well as the chemicals they have on site. Facilities may be selected for auditing based on location, quantities of chemicals on site, specific chemicals, or other criteria. A central source of information on which facilities are covered, for which chemicals, and in which industries is essential to apply criteria for selecting facilities for audits in an equitable manner. Finally, although many of the facilities file similar information with EPA, no current source of data includes all facilities likely to be affected by the proposed rule. EPCRA section 313, for which a national database exists, covers only manufacturers and does not include many of the chemicals proposed for listing. Some of the facilities will be permitted under RCRA, but most will

not be. Except for facilities not covered by OSHA's Hazard Communications Standard, most other facilities potentially affected by this proposed rule are also covered by EPCRA section 312. However, EPA does not receive section 312 data. Because these data are primarily used at the local level, only a few states have created section 312 databases. In addition, in many states facilities are not required to file chemical-specific information under section 312. Even if every state had a section 312 database, it would not be possible to identify facilities potentially covered by this proposed rule with the section 312 data. Consequently, a separate registration is needed.

EPA considered requiring an earlier registration to help identify potentially affected facilities and disseminate guidance to them. An earlier registration (either 12 months or 24 months after the date of promulgation) would also help states determine the scope of their implementation programs. EPA requests comments on whether an earlier registration would be beneficial.

Implementation

EPA has two main concerns about the implementation of the registration requirement: that multiple or duplicative filings be avoided to the maximum extent possible and that the burden for processing the information be minimized. EPA requests suggestions on how the registration information might be combined with other forms facilities are required to file to limit the repetitive reporting required of facilities. For example, EPA is considering using the EPCRA section 312 Tier II form as a substitute because the Agency believes this would facilitate integration of CAA activities with SARA Title III activities and would lessen the burden on facilities.

EPA's second concern involves the burden on the government to process the information filed. Each registration will include information that would need to be screened for accuracy. For example, the Chemical Abstract Service (CAS) number and chemical name would need to be checked to make sure that they match and are covered by the rule. SIC codes, Dun and Bradstreet numbers, and quantity range codes would need to be reviewed to ensure that the format (number of digits) and codes were acceptable (i.e., that valid codes were used). Such review could place a substantial burden on EPA and states. EPA is, therefore, considering developing software that would allow electronic filing of the information. The software would perform the quality control function automatically. CAS numbers would be checked to see if they were on the list; the chemical name could then be entered automatically. A list of known synonyms for the listed substances could be included. SIC codes could be checked to ensure that the codes entered actually exist; the format for Dun & Bradstreet numbers could also be reviewed. Messages alerting the facility that the information entered was not acceptable would be provided. Such a computerized form would lessen the time needed to process the information; it would also provide facilities with a quick check on the accuracy of their information and assure them that the data would be accurately represented in EPA's database. If facilities used such a computerized filing, however, they would still need to submit a signed certification. EPA recognizes that some facilities may not be computerized or may prefer to file a printed form. Although EPA would prefer a computerized filing, printed forms would be acceptable.

EPA requests comments on its plan to encourage computerized filings and specifically solicits suggestions on how such filings could be coordinated with other information filed on disk. For example, are there other software packages for computerized EPA filings that the RMP registration should be compatible with to facilitate data sharing and limit the amount of rekeying facilities would have to do?

G. Prohibitions

CAA section 112(r)(7)(E) states that after the effective date of the risk management program regulations it shall be unlawful for any person to operate any stationary source subject to the regulations in violation of the requirements of the regulation. Violations of the risk management program and other regulations promulgated under CAA section 112(r)(7) are subject to the same penalties as violations of National Emissions Standards for Hazardous Air Pollutants (NESHAPs) promulgated under CAA section 112(d). Persons in violation of the requirements may be subject to civil penalties of not more than $25,000 per day per violation as well as criminal penalties. Civil penalties may be assessed through court actions or through administrative orders under section 113 of CAA.

H. Timing

The proposed rule must be promulgated by November 15, 1993, and will be effective three years after the date of promulgation. EPA is setting a 120-day comment period and will hold a public hearing in Washington, DC, to solicit comments.

IV. Comparison of EPA's Proposed Rule to OSHA's Standard

A. Differences Between EPA's Proposed Rule and OSHA's Standard

The primary differences between today's proposed rule and OSHA's process safety management standard are the result of the different statutory requirements for the two rules. The CAA requires EPA to include several elements in its regulation that are not mandated for OSHA. Specifically, EPA's rule must include a hazard assessment, an emergency response program with certain elements, registration, and the submittal and auditing of the RMP. The only other element EPA is proposing that is not included in the OSHA standard is the requirement for the owner or operator of a facility to define its management system and name the person or position responsible for the program. EPA considers the management requirement critical to ensuring that the risk management program elements are integrated with each other on an ongoing basis. EPA expects that this requirement will create no additional burden for facilities because the proposed section would only require facilities to provide the name or names of people or positions responsible for implementing the program.

EPA's proposed hazard assessment includes an offsite consequence analysis and a five-year accident history, as required by the CAA. Under the OSHA standard, facilities are required to develop an onsite consequence analysis. Most of the information needed to define accidental release scenarios will be derived from the process hazard analysis, which would be the same under the two rules. The main differences under the EPA rule would be the need to use air dispersion models to analyze the distances releases might migrate and the need to document the areas potentially affected by the releases. EPA's hazard assessment also is required to include a five-year release history, which would overlap to some degree with a requirement in the OSHA's process hazard analysis.

EPA's proposed emergency response provisions respond to the language in the CAA and are somewhat different from the OSHA requirement. Under the OSHA standard, facilities must comply with one of two existing OSHA standards. Facilities that are currently in compliance with OSHA's Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120)

are likely to be in substantial compliance with EPA's proposed rule. OSHA's emergency action plan regulation (29 CFR 1910.38(a)) basically requires an evacuation plan. The CAA requires EPA's emergency response program to include "specific actions to be taken in response to an accidental release of a regulated substance so as to protect human health and the environment" (CAA section 112(r)(7)(B)(ii)). Therefore, facilities that currently have only an emergency action plan required under 29 CFR 1910.138(a) would, under EPA's proposed rule, need to develop a more extensive emergency response plan that details how the facility would respond to a release to limit offsite consequences. EPA is also proposing that facilities conduct drills and exercises to test their plans. Without such exercises, a facility will not be certain that a plan can be implemented properly during an emergency. All facilities covered by the EPA rule would need to coordinate their plans with the LEPC, which is not required by the OSHA standard. EPA considers this coordination essential to protect the public. Many facilities are already coordinating their plans with the LEPC plans and with local emergency responders. Therefore, EPA does not anticipate that this requirement will add substantially to the burden for most facilities.

The final differences between the two rules are the proposed requirements for registration, submission, and auditing of the RMP. CAA section 112(r)(7)(B)(iii) mandates these requirements. The information in the RMP would be derived from the documentation required elsewhere under the EPA proposed rule or OSHA's standard. Consequently, EPA expects that the RMP will not add substantially to the burden of complying with the rules.

See Section X of this Preamble for a discussion of the incremental burden imposed by the EPA rule over the OSHA rule.

B. Section by Section Comparison of the EPA Prevention Program and the OSHA Standard

Except for the management system requirement discussed above, the proposed EPA prevention program covers the same elements as OSHA's process safety management standard and generally uses identical language except where the statutory mandates of the two agencies dictate differences. EPA has added introductory paragraphs to most sections to provide further information to the regulated community; these paragraphs impose no additional requirements and are intended to clarify the purpose of the section's requirements and the level of detail expected of different types of facilities. In addition, EPA has made editorial changes in the OSHA language to make the rule consistent with the CAA's statutory language. Specifically, where OSHA uses the word "employer," EPA would use "owner or operator," which is defined in the CAA. Where OSHA uses "highly hazardous chemicals," EPA would use "regulated substance." Where OSHA uses "facility," EPA would use "stationary source." Where OSHA uses "standard," EPA would use "rule." Finally, where OSHA references workplace impacts, EPA would reference offsite consequences, reflecting the different statutory mandates of the two agencies.

The specific parallel elements of the two rules are as follows:

- EPA's process hazard analysis requirement (§ 68.24) is the same as OSHA's process hazard analysis requirements (29 CFR 1910.119(e)), with the following changes: (1) An introductory paragraph; (2) the priority order for conducting the analysis would consider offsite consequences rather than the number of potentially affected employees; (3) OSHA's schedule for implementation would not be included because the CAA requires that facilities comply with EPA's rule within three years of the date of promulgation and, therefore, OSHA's five-year schedule could not be used; (4) the identification of previous incidents would be limited to those with offsite consequences rather than those with catastrophic consequences in the workplace; and (5) the qualitative evaluation of safety and health impacts would focus on impacts on public health and the environment rather than on employees. EPA expects that, in most cases, fewer incidents will need to be considered under EPA's proposed rule because releases are generally more likely to affect workers rather than the public. However, some types of releases, such as the release at Bhopal, have their primary impact off site. EPA's rule would ensure that these potential releases are evaluated. Finally, in response to the statutory requirement that the prevention program include monitoring, EPA would add a paragraph (j) requiring facilities to evaluate monitors, detectors, containment or control devices, and mitigation systems.
- EPA's proposed process safety information (§ 68.26) is identical to OSHA's process safety information system (29 CFR 1910.119(d)) except for editorial changes and the requirement, in paragraph (c)(5), that the evaluation of the consequences of process deviations include those affecting public health and the environment rather than workers.
- EPA's standard operating procedures requirement (§ 68.28) is identical to OSHA's operating procedures (29 CFR 1910.119(f)) except for the introductory paragraph and editorial changes.
- EPA's training section (§ 68.30) is identical to OSHA's training section (29 CFR 1910.119(g)), except for the introductory paragraph, editorial changes, and a requirement that facilities evaluate the effectiveness of their training programs and revise the programs, if necessary, based on the evaluation.
- EPA's maintenance requirements (§ 68.32) uses the same language as OSHA's mechanical integrity paragraph (29 CFR 1910.119(j)) with certain exceptions. EPA would use the term "maintenance" rather than "mechanical integrity" to parallel its statutory language. EPA would add an introductory paragraph and make editorial changes. In paragraph 68.32(b), EPA would require the facility to develop a list of equipment that requires maintenance; the OSHA standard provides a list of equipment. EPA's paragraph (b) includes the OSHA list, but EPA is concerned that for some facilities the list may be too extensive and for others it may not be comprehensive. For example, for warehouses, the only equipment that may need maintenance may be the sprinkler system and the forklifts, neither of which are on the list. EPA believes the responsibility should be on the facility to develop a list, based on specific facility concerns. EPA would also add an opening paragraph to the OSHA paragraph on inspections and testing and include the word "maintenance" before inspection and testing throughout the paragraph. The inclusion of the word "maintenance" would clarify that equipment should be maintained on e regular basis; for some equipment simple routine maintenance, such as cleaning and oiling, may be all that is necessary; other equipment, such as seals, may be replaced on a regular schedule. EPA's revision would clarify that such maintenance is included in the inspection and testing requirement. EPA would also add language to clarify that training of maintenance workers would be documented in the same manner as other training.
- EPA's pre-startup review requirement (§ 68.34) is identical to OSHA's pre-startup review paragraph (29 CFR 1910.199(i)) except for editorial changes, the introductory paragraph, and the requirement in paragraph

68.34(c)(4) that maintenance as well as operating employees are trained prior to startup and that all employees are trained on any new emergency response procedures. EPA believes these additions are necessary to ensure the safety of the facility.

• EPA's management of change requirements (§ 68.36) are identical to OSHA's paragraph (29 CFR 1910.119(l)), except for the introductory paragraph, editorial changes, and a new paragraph (b) in which EPA defines alterations that do not constitute a change. Paragraph 68.36(b) is intended to clarify what constitutes a replacement in kind. EPA would also change paragraph (d)(2) to replace OSHA's "impact of change on health and safety" to "impact of change on likelihood of a significant accidental release."

• EPA's safety audit requirement (§ 68.38) is identical to OSHA's compliance audit paragraph (29 CFR 1910.119(o)), except for the introductory paragraph and editorial changes.

• EPA's accident investigation requirements (§ 68.40) are identical to OSHA's incident investigation paragraph (29 CFR 1910.119(m)), except for: (1) The introductory paragraph and editorial changes to substitute the phrase "significant accidental release" for the word "incident"; (2) the addition, in paragraph (b), of a requirement that the procedures be written; (3) the requirement in paragraph (c) that incidents that require investigation are those that caused or could have caused offsite consequences rather than catastrophic releases in the work place; and (4) the addition, in paragraph (f)(4), that the facility identify root causes as well as initiating events.

The OSHA standard includes several requirements that are not covered by EPA's proposed rule—worker consultation, hot work permits, contractor rules, and trade secrets. EPA believes that worker consultation and hot work permits are worker protection issues and are, therefore, properly in OSHA's area of concern. EPA's trade secret rules for the CAA already are covered in 40 CFR part 2.

Finally, although EPA recognizes the importance of contractor competence on safety, EPA believes this issue is primarily one that OSHA should address, as it has in its section on contractors. In addition, EPA believes that contractors are mainly an issue at larger companies, most of which are covered by the OSHA standard. EPA requests comments on whether EPA should adopt OSHA's contractor paragraph as part of the risk management program requirements.

As specified in CAA section 112(r)(7)(B)(i), EPA's rule would become effective three years after the date of promulgation. OSHA's rule will allow facilities up to five years to conduct process hazard analyses. Because the OSHA standard was promulgated prior to EPA's rule, however, EPA does not anticipate that the actual compliance dates for the two rules will differ significantly.

V. Relationship to Other Federal and State Requirements

Federal Regulations

A number of the facilities potentially affected by today's proposed rule are also covered by other Federal requirements that may relate to practices that will be included in the risk management program. As discussed in the section on emergency response, several EPA programs require facilities to develop emergency response plans. These programs include the Resource Conservation and Recovery Act requirements and the Spill Prevention, Control, and Countermeasure requirements under the Clean Water Act. In addition, loading and unloading of hazardous materials for transportation are covered by DOT regulations, as are storage incident to transportation and repackaging for resale and transportation. The DOT regulations are particularly likely to affect distributors and warehouses. EPA requests comments on how these requirements can be harmonized to eliminate conflicts and minimize duplication. Specifically, EPA requests comments on whether compliance with other Federal regulations will meet some or all of the requirements of the proposed rule and, if so, how the rule should acknowledge this fact to ensure that facilities understand what, if any, additional steps they must take to come into compliance with the risk management program requirements.

State Laws

Four states—California, New Jersey, Delaware, and Nevada—have implemented state laws that require certain facilities to develop risk management programs. Although the existing state programs differ in some respects, they address the same basic elements that EPA is proposing in this rulemaking, except that the California program does not specify a management of change procedure. The New Jersey Toxic Catastrophe Prevention Act (TCPA) program is the most detailed program, specifying to a considerable degree the information required to be developed and submitted; New Jersey also requires that workers pass competency tests after training. The Delaware program provides facilities with more flexibility by specifying less detailed requirements. The California program is the most general of the programs; the California risk management plan program developed by each affected facility is driven by the results of the process hazard analysis, rather than responding to a set of specific mandated requirements.

The primary differences in the state programs relate to their implementation and the chemicals covered. New Jersey, Delaware, and Nevada have implemented their programs at the state level. California has delegated implementation authority to more than 100 administering agencies, which are usually the fire or health departments. New Jersey, California, and Nevada require facilities to submit their plans to the administering agencies for review and approval. Delaware requires facilities to maintain the plan and documentation on site for state inspectors. California also allows the administering agencies to exempt facilities that meet the thresholds if the agency determines that the facility does not pose a significant risk to the community.

Each of the states has a different list of chemicals and thresholds. New Jersey's list covers 109 acutely toxic substances; Delaware covers 90 toxic substances, as well as flammables and explosives; California covers all 360 of the EPCRA section 302 list of extremely hazardous substances; Nevada adopted OSHA's list of highly hazardous chemicals. California uses EPA's threshold planning quantities (TPQs) as thresholds for notification and allows local agencies to decide whether a facility must comply; New Jersey and Delaware developed separate and different methodologies for calculating thresholds; Nevada adopted OSHA's thresholds. None of the state lists is entirely consistent with EPA's proposed list.

EPA anticipates that facilities currently in compliance with the New Jersey, Delaware, and Nevada regulations will be in compliance with most elements of today's proposed rule. Because the California rules are more general and because different administering agencies have interpreted the requirements differently, it is not possible to determine, except on a case-by-case basis, to what extent a California facility will be in compliance with EPA's rule.

The Clean Air Act section 112(l) allows EPA to delegate the implementation of the risk management

program to states that have an approved program. The criteria for state programs are listed in CAA section 112(l)(5). The Act allows states to adopt the Federal program or implement a program that is more stringent. Consequently, the existing state programs will require some revisions to meet EPA's requirements or set more stringent requirements than those established by the EPA rule. EPA expects that most of the needed changes will involve the listing of chemicals and adjusting of thresholds. Other states that are developing state programs to implement these regulations should determine whether they have sufficient statutory authority under their air or emergency planning/community right-to-know SARA Title III programs to adopt the requirements of these regulations. EPA will provide additional guidance for states before the final rule is promulgated.

VI. Other Approaches Considered

The CAA requires facilities that have a regulated substance in quantities greater than the threshold to develop and subm... RMPs. EPA recognizes that, for small facilities, even the less complex risk management program that would be needed for simple processes could create a substantial burden. EPA considered three approaches, therefore, that might reduce this burden. Each of these approaches would create two tiers of risk management programs, a minimal program and an expanded risk management program. The approaches differ on how facilities would be divided between the two tiers.

The first approach considered would be to develop criteria for determining when facilities needed an expanded risk management program. The criteria could be as simple as a multiple of threshold quantity (e.g., an expanded risk management program would be required at 10 times the threshold quantity), or would combine the quantity on site with other factors such as distance to the fenceline, proximity of sensitive populations (e.g., hospitals, schools, residences), similar to the approach used in Delaware. EPA decided not to propose this approach for several reasons. Facility operators in Delaware and state officials report that this approach is difficult to implement because considerable technical expertise is needed and many smaller facilities and non-manufacturers do not have the expertise in house. In addition, developing a set of criteria that would be appropriate in all situations may not be possible because too many factors influence the hazard posed by a particular process and substance. Using the simple multiple of the threshold quantity would ignore the dangers posed by relatively small quantities of regulated substances in specific circumstances.

The second approach considered would be to have facilities determine whether they needed an expanded risk management program based on the offsite consequence analysis: If the worst-case release could not expose the public or the environment to significant risks, the facility would not need an expanded risk management program. Although this approach is a better way to determine whether the potential risks of a facility merit an expanded risk management program, it is fraught with problems. This approach would create considerable potential for debate and legal disputes over the assumptions facilities use to determine offsite consequences. Assumptions appropriate for one facility or area may not be appropriate for others. EPA believes that this approach would leave facilities uncertain of the legal status of their decisions and create difficulties for enforcement by governments and citizens. In addition, given the experience of Delaware facilities, it is likely that many smaller facilities and those outside the manufacturing sector would have substantial difficulty understanding and implementing this approach. EPA notes that most of the facilities potentially affected by the proposed rule are non-manufacturers; less than five percent of the potentially effected facilities are chemical manufacturers or petroleum refineries.

The final approach considered would be to follow the California model and let local or state agencies decide which facilities pose the greatest threat and, therefore, require an expanded risk management program. EPA believes that local agencies are in the best position to identify and evaluate local hazards. However, the viability of this approach rests on the ability and willingness of state or local groups to make these decisions. This approach would impose a considerable burden on state and local authorities. It could also lead to the uneven imposition of requirements on facilities if states or localities chose to cover facilities differently. Some facilities already covered by risk management program rules believe that they have been placed at a substantial competitive disadvantage because they are complying with the state law, while similar facilities in other states are not. An uneven implementation also leaves the protection of the public uneven.

EPA requests comments on these approaches and methods that could be used to create tiers in risk management program requirements. EPA also requests comments on what a "minimal program" would be, given the Congressional mandate that requires the risk management program to include a hazard assessment, a prevention program that includes safety procedures, maintenance, monitoring, and training, and an emergency response plan.

VII. Guidance

The CAA requires EPA to publish, when the final rule is promulgated, guidelines to assist facilities in the preparation of risk management programs. The guidelines shall, to the extent possible, include model RMPs. EPA is aware that for many facilities, especially those outside the chemical and petroleum refining industry and many smaller facilities, the risk management program approach and some of the elements will be unfamiliar. EPA intends, therefore, to provide as much guidance as possible and to encourage trade associations, professional organizations, labor, and others to develop and disseminate appropriate guidance as well. EPA requests comments on areas where guidance is needed (e.g., process hazard analyses, maintenance programs), the levels at which guidance should be directed, and appropriate formats for the guidance.

EPA has identified industry sectors that may be candidates for model risk management programs. Generally, most of the covered facilities in these sectors are using the same chemical in the same way, with similar types of equipment. The similarity will allow EPA to develop guidance on the chemical and process hazards, identify typical hazards that need to be considered in the process hazard analysis, suggest areas that should be covered in SOPs and training, identify critical equipment for maintenance programs, and describe model emergency response procedures. The purpose of the guidance will not be to provide facilities with an "off-the-shelf" plan, but rather to provide a framework that the facility can use to analyze its own operations and develop a program to manage risks.

Industry sectors that may be appropriate for model risk management programs include chlorine and ammonia users such as public drinking water systems and wastewater treatment works, cold storage facilities, wholesalers, and propane retailers. EPA requests suggestions for other industry groups for which model risk management programs may be possible.

VIII. Information Gathering Efforts

Before EPA began writing its proposed rule on risk management programs, the Agency decided to seek information from those already implementing risk management program regulations. EPA staff met extensively with officials in the three states and held interviews with seven facilities that have developed risk management programs under state laws. To gather more information, EPA held eight focus groups, five with facilities (two each in New Jersey and California, one in Delaware), and three with administering agency officials in California, to elicit their opinions of the risk management program regulations in their respective states and their ideas about what EPA should consider as it develops its program. After analyzing the results of these meetings, EPA and the National Governors' Association sponsored a two-day seminar on issues that have arisen at the state level. Officials from California, Delaware, and New Jersey, as well as New York, Minnesota, and Wisconsin attended the meetings. On the second day, other groups including trade associations, professional organizations, labor, and environmentalists joined the discussion.

Several industry participants believed that the risk management program process is improving safety, although the initial costs are high. Many considered the most costly element, the process hazard analysis, the most important because it identifies hazards and allows facilities to set priorities. Larger facilities, especially those in the chemical and petroleum industries, currently have more risk management program elements in place than do smaller facilities. Larger facilities are also more able to implement the program with their own staff; smaller facilities often lack the in-house expertise to develop and implement all risk management program elements. Various industry participants recommended that the risk management program regulations give facilities the flexibility to tailor a program to their own situations. According to these participants, the regulations should tell a facility what to do, not how to do it. Many participants with various perspectives recommended that regulations be specific enough to limit inconsistent interpretation either across states or among inspectors. Inconsistently applied regulations create competitive disadvantages and undermine the willingness of facilities to comply. Many participants from various sectors expressed the view that guidance and technical assistance will be needed at the state, local, and facility levels, and that education and outreach efforts will be necessary. Several industrial and governmental participants said that to the extent possible, the OSHA, EPA, and state regulations and chemical lists should be consistent. The same participants believed that facilities would like to ensure that if they are in compliance with one rule, they would automatically be in compliance with all rules, at least for a specific chemical. There was a general concern that the expertise to implement the program may not be uniformly available in the short-term. This lack of expertise will affect both facilities and government agencies.

A report on this information gathering effort entitled *Clean Air Act of 1990, Chemical Accident Release Provisions, Report on Focus Groups and Round Table Discussions* is available in the docket as are transcripts of the eight focus groups.

IX. Section by Section Discussion of the Proposed Rule

EPA is proposing to add a new part 68 to 40 CFR, which would include the risk management program requirements, as well as the list of regulated substances and related regulations, and any additional chemical accident prevention regulations that EPA may promulgate in the future. This section reviews the regulations that would be added in this rulemaking.

Proposed § 68.1 would define the scope of the part.

Proposed § 68.3 would provide definitions applicable to the Part.

Proposed § 68.10 would define the applicability of the risk management plan requirements to all stationary sources where a regulated substance is present in a process at any one time in more than the threshold quantity. The section also includes the effective dates for the risk management program elements. Facilities would be required to develop and implement all risk management program elements within three years of the date of promulgation of the rule or within three years of becoming subject to the rule (i.e., three years after the facility introduces a new regulated substance to its operations or a new substance is listed).

Proposed § 68.12 would define the requirements for registration. Facilities would be required to register three years after the date of promulgation of the rule or within three years of date on which the facility becomes subject to the rule (either because the facility introduces a new regulated substance to its operations or a new substance is listed). If the information submitted on a registration form is no longer accurate, facilities would be required to update the information within 60 days of the change.

Proposed § 68.15 would provide the requirements for the hazard assessment. Facilities would be required to complete a hazard assessment for each regulated substance present in greater than a threshold quantity. For each such substance, a worst-case release scenario would have to be defined. The offsite consequences of a range of release scenarios, including the worst-case and other more likely significant accidental release scenarios, would have to be analyzed. The proposed section specifies a number of scenarios that should be considered and the information that must be included in the offsite consequence analyses. The section also would require the facility to develop and maintain a five-year history of significant accidental releases and releases with the potential for offsite consequences for each regulated substance. The hazard assessment would have to be reviewed and updated every five years, unless changes necessitated an update sooner. The section would detail the documentation that would be required to be maintained on site.

Proposed § 68.20 would explain the purpose of the prevention program and specify that the ten elements of the program must be tailored to suit the degree of hazard present at a facility and the degree of complexity of the operations.

Proposed § 68.22 would require facilities to designate a person or position responsible for overseeing the development and implementation of the prevention program elements. Where other individuals are responsible for separate elements, an organization chart showing lines of authority would be required.

Proposed § 68.24 would detail the requirements for the process hazard analysis. A process hazard analysis would be required for each location where regulated substances are present above the threshold quantity. Formal process hazard analysis techniques would have to be applied, with the complexity of the process and potential consequences of a release to be considered in selecting an appropriate technique. The section would require facilities to conduct evaluations on the most hazardous locations first.

The process hazard analysis team would be required to report findings and recommendations to management. The facility management would be required to document its response to each finding and recommendation, and

maintain a schedule for implementing actions to address findings. If the facility management decides not to implement certain recommendations, a rationale for the decision would have to be documented.

Based on the process hazard analysis results, the facility would be required to evaluate and develop a plan for (or a rationale for not) installing detection and alarm systems, secondary containment and control systems, and mitigation systems. The process hazard analysis would have to be reviewed and updated every five years unless changes of chemical use, process technology, or equipment require an earlier review and revision.

Proposed § 68.26 would require the facility to develop and maintain up-to-date chemical, technology, and equipment information. Technology information would include process flow diagrams and process chemistry information, maximum intended inventories for vessels, process parameters, and consequences of deviations from parameters. Equipment information would include materials of construction, electrical classifications, material and energy balances, design bases and codes, safety equipment designs, and diagrams of piping, equipment, and controls. The owner or operator would have to document that equipment complies with good engineering practices.

Proposed § 68.28 would require facilities to develop and maintain written procedures for operations.

Proposed § 68.30 would require facilities to develop and implement training programs to ensure that all employees are trained in SOPs that apply to them. Refresher training would be required at least every three years. The facility would have to develop a method of ensuring that each employee is competent. In addition, facilities would be required to evaluate the effectiveness of their training. Based on this evaluation, the facility would be required to develop and maintain a schedule for revising the training program. All training conducted at the facility would be documented. In lieu of initial training, the facility could certify that current employees have the knowledge and skills to carry out the SOPs.

Proposed § 68.32 would require facilities to develop a list of equipment and controls whose failure could lead to a significant accidental release of a regulated substance. For items on the list, a maintenance program that included a schedule for inspections, testing, and maintenance would be required. Inspection and testing procedures and schedules would be based on manufacturers' recommendations unless industry or facility experience indicated that more frequent inspections and tests, or different procedures were needed. Written maintenance procedures and training of maintenance workers would also be required. Equipment found to be outside acceptable limits would have to be replaced or repaired prior to being used again or in a timely manner that ensures safety. Procedures to ensure that replacement equipment is installed properly and consistent with design specifications would be required. Records of each inspection, test, repair, and replacement would be required.

Proposed § 68.34 would require facilities to develop procedures to ensure that a pre-startup review is conducted before a new or modified process is brought online. This section would not apply to routine startups after shutdowns for maintenance provided standard procedures are developed for such startups. The pre-startup review would confirm that all installations and changes meet design specifications, that SOPs and maintenance programs are in place for the new processes, and that employees have been trained. Records of each startup, including actions taken to address any problems uncovered during the review, would be maintained at the facility under § 68.55.

Proposed § 68.36 would require facilities to develop management of change procedures to ensure that any alteration of chemicals, processes, and procedures are reviewed prior to implementation. Replacement of equipment or controls with a device that meets the design specifications of the replaced device would not be considered a change. The procedures would ensure that the technical basis of the change is documented and that the consequences of the change are evaluated. Process safety information and the process hazard analysis would be updated as needed, as would SOPs, training, and maintenance programs. The results of each such review would be maintained at the facility under § 68.55.

Proposed § 68.38 would require facilities to conduct safety audits every three years. Each audit would be documented in a report with findings and recommendations. Management's response to each finding and recommendation would be documented, with a schedule for implementation or a rationale for not implementing.

Proposed § 68.40 would require facilities to develop and implement procedures to investigate each significant accidental release. Investigations would have to start within 48 hours of the accident. The investigation would document, in a report to management, the initiating event, root causes, and recommendations for preventing recurrences. Management would be required to document its response to each recommendation, with either a schedule for implementation or a rationale for not implementing the recommendation. The results of the investigation would have to be reviewed with all potentially affected employees.

Proposed § 68.45 would require facilities to develop a written emergency response plan that would specify procedures for employees not involved in a response action, procedures for responders, a list of all response and mitigation technologies. The plan would also include procedures for notifying and alerting the public and public response agencies. The facility would be required to have procedures for the use, inspection, testing, and maintenance of response equipment. The facility would also develop information on first aid and emergency health care related to potential exposures. Employees would be trained in applicable response procedures. Facilities would be required to conduct drills or exercises to test the plan. Any drill or exercise would be documented, with findings relevant to plan revisions; management would be required to document responses to the findings, with schedules for implementation. The emergency response plan would be coordinated with the local emergency planning committee's community plan prepared under SARA Title III.

Proposed § 68.50 would require submission of the RMP containing a copy of the facility's registration form, hazard assessments for each regulated substance (i.e., worst-case scenario, offsite consequences for a range of more likely significant accidental release scenarios, and five-year history of significant accidental releases), a list of major hazards identified through the process hazard analysis, the consequences of failure to control each major hazard, steps being taken to address the hazards, implementation schedules, a summary of other prevention elements, a description of the emergency response plan, a description of the management system for implementing and integrating the risk management program, and a certification of accuracy and completeness. The RMP would be revised and resubmitted every five years unless changes dictate a more frequent revision.

Proposed § 68.55 would specify which records would need to be maintained and that records would be maintained for five years. Facilities would also be required to maintain implementation schedules for recommendations from the process hazard analysis, safety audit, and accident investigation.

Proposed § 63.60 would specify the audit system for reviewing RMPs.

X. Regulatory Costs and Benefits

Agencies proposing and promulgating regulations must consider both the costs and benefits of those rules on the affected community. This section summarizes the analyses conducted in support of this proposed rule and the list and threshold rule. The full regulatory impact analysis (RIA), entitled "Regulatory Impact Analysis in Support of Listing Regulated Substances and Thresholds and Mandating Risk Management Programs for Chemical Accident Release Prevention, as Required by Section 112(r) of the Clean Air Act," is available in the docket.

As mentioned above, the cost information in this section is based on an analysis of this proposed rule and the list and threshold rule. Since the RIA was completed, the Agency has collected new cost information from comments to the proposed list and threshold rule and has conducted additional analyses. The revised cost information is contained in an addendum to the RIA, which is available in the docket. The Agency recognizes that the costs/benefits and the universe of affected facilities are difficult to estimate accurately and requests comments and input on the RIA and the addendum. Specifically, EPA requests comments on the unit-cost estimates for the prevention program elements and rate of current compliance with these elements.

Options Considered

To evaluate alternatives, EPA analyzed five list and threshold options and two risk management program options. The five list options were: List 1—101 acute toxics at the proposed thresholds; List 2—EPA's proposed list (100 toxics, 62 flammables, and high explosives) at the proposed thresholds; List 3—EPA's proposed list at the EPCRA section 302 threshold planning quantities (TPQs) where applicable; List 4—the full EPCRA section 302 list at the TPQs; and List 5—the full EPCRA section 302 list of extremely hazardous substances at the threshold planning quantities, plus 62 flammables and high explosives. The options were selected to bound the different combinations of chemicals and threshold quantities that were under consideration by EPA during development of the proposed list regulation. The OSHA list was not included as a listing option because it includes some substances that EPA is statutorily prohibited from listing, it does not include many acutely toxic chemicals that meet EPA's criteria for listing, nor does it include all statutorily mandated regulated substances. In addition, many of the substances listed by OSHA are reactives, which EPA has not determined pose a significant hazard to the public in the event of an accidental release.

The RIA also considered two options for risk management program requirements: EPA's proposed rule; and a more stringent version of the proposed rule, modeled on the New Jersey state regulations, which are more detailed and impose more specific requirements for many of the risk management program elements. The OSHA standard was not considered because it does not fully meet the statutory mandate for EPA's risk management regulation.

Methodology

To estimate the universe of potentially affected facilities under each list and threshold option, EPA used 1988 data from the New Jersey Right-to-Know database. Under the New Jersey Right-to-Know statute (New Jersey Pub. L. 1983, Chapter 315), facilities are required to complete surveys of chemical inventories if they have any amount of the listed substances on site. Facilities are required to report the maximum quantity on site for each covered substance and the CAS number for the substance; all of the toxic substances EPA considered for listing are on the New Jersey list. Facilities also are required to report applicable four-digit SIC codes and the number of facility employees. Although there are limitations and cautions that must be exercised when extrapolating state data to estimate national impacts, EPA believes that the New Jersey data provide comprehensive coverage of SIC codes, including the majority of four-digit SIC codes across both the manufacturing and non-manufacturing sectors, and are reasonably representative of chemical use patterns throughout the nation. In addition, New Jersey facilities are required to report on inventories of all acutely toxic chemicals covered by EPA's listing options. Further, the information in the New Jersey database on number of employees allows disaggregation of the data by facility size. There are, however, limitations to the New Jersey data; to the extent possible, EPA augmented the New Jersey data to adjust for these limitations. For example, because facilities in New Jersey are not required to report on flammables, data from Louisiana's EPCRA section 312 database were used to develop estimates of the number of additional facilities that would be covered because of the listed flammables. Similarly, certain industrial sectors were clearly underrepresented in the New Jersey data; adjustments were made wherever possible to correct for these limitations.

The New Jersey database was searched by four-digit SIC code to identify for each such code the number of facilities that reported a listed toxic chemical above the threshold. The number of reports of regulated substances per four-digit SIC code was also obtained from the New Jersey data. The information obtained from these searches was compared with the number of facilities in each four-digit SIC code in New Jersey (based on 1989 County Business Pattern data). The ratio of the number of facilities reporting the presence of the chemicals above the proposed thresholds to the number of facilities in the SIC code in the state was extrapolated to the nation to estimate the number of facilities in each SIC code potentially affected by the proposed rule. The ratio of the number of regulated substances reported per facility in New Jersey in each four-digit SIC code was used to estimate the number of hazard assessments that would likely be required under each listing option. The Louisiana data were used to identify those four-digit SIC codes where the addition of flammables would result in additional facilities and additional chemicals per facility covered by EPA's regulatory options.

Three industry sectors were substantially underrepresented in the state databases: public facilities, cold storage facilities, and propane retailers. To adjust for this underrepresentation of public facilities, the analysis used EPA data on public drinking water systems and publicly owned treatment works to estimate the number of public facilities potentially affected by the proposed rule. Industry information was used to estimate the number of cold storage facilities (i.e., food processors, food distributors, and refrigerated warehouses) and the number of propane retailers.

In Delaware and New Jersey, 30 percent and 52 percent of the facilities (respectively) that initially registered under the state laws lowered inventories or switched chemicals to avoid having to comply with the risk management program requirements. Based on this experience, EPA assumed that 30

percent of the facilities in most manufacturing, utility, and service industries would take similar steps to avoid being affected by EPA's proposed rule. The final estimates of the number of affected facilities in these sectors were adjusted to account for this expected change in chemical use. The number of chemical manufacturers, wholesalers, and propane distributors was not adjusted downward; facilities in these sectors were assumed to be unable to reduce inventories sufficiently to avoid coverage because of the nature of their businesses.

To develop cost estimates, affected manufacturing facilities (SIC codes 20–39) were classified as small, medium, and large, based on the number of employees. For each SIC code, manufacturing facilities were also categorized as likely to have simple, moderately complex, and complex processes, based on categories developed by OSHA for its process safety management standard. Facilities outside the manufacturing sector were divided into six categories: public drinking water and treatment works; private utilities (SIC code 49—electric and gas utilities); cold storage facilities that use ammonia as a refrigerant (SIC codes 20, 4222, 514); wholesalers (SIC codes 50–51); retailers, which are primarily propane distributors; and others (primarily service industries (SIC codes 70–89)). Non-manufacturers were assumed to handle the regulated substances in simple ways and to have available EPA model risk management programs or guidance, described in Section VII of this preamble, that would lessen the burden of compliance. Wholesalers and cold storage facilities were divided into small and large facilities based on the quantity of chemicals on site because the complexity of implementing the rule is assumed more likely to be related to the quantity of the chemicals on site rather than the number of employees at a facility. For example, some chemical distributors have more than 100 million pounds of a substance on site, but employ fewer than 20 people, only some of whom handle the substance. Public and private utilities were assumed to be small because a limited number of employees are assumed to handle regulated substances.

Using industry experience and engineering expertise, cost estimates were developed for each risk management program element for each class and category of facility. Costs were developed on a per chemical, per process, per release, or per facility basis for each element of the program, as appropriate. Because many facilities already implement some of the risk management program requirements (e.g., training, emergency response plans), costs were adjusted to account for current compliance, based on compliance estimates for each risk management program element developed by EPA, OSHA, an American Paper Institute study of the actual level of current compliance among its members, and experts in the cold storage industry.

For final cost calculations, facilities were divided into two further groups: those covered only by the EPA rule, who would be subject to the full cost of complying with all elements of the proposed rule, and those covered by EPA and OSHA, who would incur costs only to implement the additional elements covered in EPA's proposed regulation (i.e., registration, hazard assessments, and the RMP). Different cost estimates were developed for publicly owned drinking water systems and wastewater treatment systems, depending on the states where the systems are located. For systems in states with delegated OSHA health and safety programs (i.e., state-plan states), only incremental costs associated with performing the hazard assessment and developing the RMP were attributed to the EPA proposed rule; these systems must already comply with state standards at least as stringent as the Federal OSHA standards. For systems not in state-plan states, the full cost of the proposed rule was assumed to be incurred. Table 1 presents the estimated number of facilities covered by each list option.

TABLE 1.—ESTIMATED NUMBER OF FACILITIES AFFECTED BY EPA'S LIST AND THRESHOLD OPTIONS

Options	Manufacturers not otherwise regulated	Manufacturers previously regulated [1]	Non-manufacturers not otherwise regulated	Non-manufacturers previously regulated	Total
List 1	3,975	18,960	28,650	64,060	115,645
List 2	3,975	18,960	48,650	68,840	140,425
List 3	13,640	19,940	54,560	68,640	156,980
List 4	19,530	20,470	37,830	64,060	141,890
List 5	19,530	20,470	57,830	68,840	166,670

[1] "Previously regulated" refers to facilities subject to the OSHA standard or to a state standard at least as stringent as the Federal OSHA standard.

EPA estimates that approximately 140,425 facilities would be affected by EPA's proposed rule. Of this universe, 87,800 would also be covered by the OSHA rule or an equivalent state standard; the costs estimated for these facilities reflect only the costs for registering and developing the hazard assessment and RMP. The remaining 52,625 facilities will only be covered by EPA's proposed rule; the estimated costs reflect the costs of implementing all risk management program requirements. The total universe of covered facilities includes 22,935 manufacturers (covering all manufacturing sectors except tobacco); 3,360 private utilities (electric and gas utilities, drinking water systems, and treatment works); 33,250 public drinking water and treatment works; 50,000 cold storage facilities; 9,460 wholesalers; 20,000 propane retailers, and 1,240 service industry facilities.

EPA estimates that the costs per facility will vary, for facilities covered solely by the EPA rule, from approximately $1,700 for a facility in the service industry sector, to approximately $153,000 for a large complex manufacturing facility. EPA did not estimate the cost of compliance for a highly complex facility such as a petroleum refinery because all of these facilities are covered by the OSHA standard. The most costly items in the prevention program for manufacturers include the process hazard analysis, which varies from $6,600 per process for a simple facility to $35,000 per evaluation for a complex facility; training costs, which vary from $2,400 for a small simple facility to $61,000 for a large (150-employee) complex facility; process and equipment information, which may cost a large facility $36,000

per process; and SOPs, which vary from $2,500 for a simple process to $14,000 for a complex process. Costs for non-manufacturers are estimated to be considerably lower both because their operations frequently do not involve special equipment and because model RMPs and guidance are assumed to be available to them, thus lessening the burden. The cost of conducting the hazard assessment is estimated to vary from $70 per assessment for non-manufacturers to $280 per assessment for large complex manufacturers; the number of assessments likely to be required is estimated to vary from one (for a cold storage facility with only ammonia on site) to 10 for a petrochemical facility. The cost of developing the RMP is estimated to range from $156 to more than $1,000 for a highly complex facility. Registration costs are estimated to very between $43 and $105, depending on the number of substances on site. Table 2 presents the average cost per facility for manufacturers and non-manufacturers. EPA estimates that the initial cost of the proposed rule would be $503 million.

EPA estimated subsequent year total costs for a period of ten years. Costs vary from year to year because certain risk management program elements are not required to be updated yearly. For example, safety audits would be conducted every three years; hazard assessments and process hazard analyses would be updated every five years. Table 3 presents the estimated costs for years one through five for the five listing options.

Benefits

The proposed risk management rule is expected to generate benefits to the regulated community and to society at large. EPA has estimated a dollar value for many of these benefits; the methodology used to generate these estimates is presented in chapter 7 of the RIA.

The benefits of the proposed risk management rule were estimated using several quantitative techniques to investigate each of the different types of benefits expected to occur. First, the proposed risk management rule is expected to reduce the number of significant hazardous chemical releases occurring each year at facilities affected by the five list options. This reduction in the number of releases was estimated using Accidental Release Information Program (ARIP) data for the four-year period 1987–1990. The trend in the number of hazardous chemical releases in New Jersey, where many of the riskmanagement program elements are required to be in place already, was compared with the trend in the number of releases in the rest of the nation. The difference between the two trends, approximately 27 percent at the end of the four-year period, provided an estimate of the magnitude of the reduction in the number of hazardous chemical releases that could be expected to occur as a result of EPA's proposed risk management rule.

The proposed rule is also expected to reduce the number of incidents of environmental damage (e.g., soil contamination, vegetation damage, and property damage), human impacts (e.g., injuries, hospitalizations, and deaths), and response actions (e.g., evacuations and sheltering in place) occurring each year as a result of releases of hazardous chemicals. These reductions were estimated by using a regression analysis with ARIP data to predict the probability that each type of environmental damage, human impact, or response action would occur as a result of a hazardous chemical release, both with and without the proposed risk management program in effect. The estimated probability that each type of incident would occur was then multiplied by the estimated number of releases under each scenario (i.e., with and without the risk management program in effect) to derive an estimate of the number of incidents causing environmental damage, human impact, or response actions that would be avoided each year at facilities affected by the proposed risk management rule. The analysis indicated that the number of incidents would decline by 35 percent or more, depending on the type of incident and the List Option selected, following implementation of the proposed risk management program. For human impacts and response actions, the estimated number of incidents was multiplied by the average number of people injured, hospitalized, evacuated, or sheltered in place to derive an estimate of the number of people affected per year by incidents of each type.

TABLE 2.—ESTIMATED AVERAGE COST PER FACILITY MANUFACTURERS

	Small-sized facilities		Medium-sized facilities		Large-sized facilities			
	Simple	Moderate	Simple	Moderate	Simple	Moderate	Complex	Highly complex
Not Otherwise Regulated	$15,430	$27,760	$33,430	$81,920	$53,750	$93,750	$153,470	
Previously Regulated	760	1,070	910	1,580	1,500	1,960	3,280	$5,720

NON-MANUFACTURERS

	Public facilities	Private utilities	Cold storage facilities		Wholesalers	Service industries	Retailers
			Small	Large			
Not Otherwise Regulated	$8,200	$8,250	$9,400	.....	$2,220	$1,860	$1,670
Previously Regulated	530	580	.....	$510	650	560	.....

TABLE 3.—SUBSEQUENT-YEAR COSTS BY LIST OPTION FOR PROGRAM OPTION 1

[$ millions]

Year	List option 1	List option 2	List option 3	List option 4	List option 5
0	$460	$503	$358	$1,004	$1,046
1	79	92	144	159	171
2	84	98	152	167	181

TABLE 3.—SUBSEQUENT-YEAR COSTS BY LIST OPTION FOR PROGRAM OPTION 1—Continued
[$ millions]

Year	List option 1	List option 2	List option 3	List option 4	List option 5
3	109	128	213	241	258
4	84	98	152	167	181
5	195	217	338	383	404

Finally, the dollar value of the benefits of the proposed risk management program were estimated by developing an estimate of the cost of each type of incident, and then by multiplying the estimated cost of each type of incident by the number of incidents avoided that may be attributed to the presence of a risk management program. The benefits of the proposed rule are estimated to be approximately $890 million per year. Table 4 presents the estimated costs and benefits for each of the list options considered by EPA during the rule development.

TABLE 4.—ESTIMATED FIRST YEAR COSTS AND BENEFITS
[$ Millions]

	Estimated costs	Estimated benefits
List option 1	$460	$836
List option 2	503	890
List option 3	858	1,539
List option 4	1,004	1,615
List option 5	1,046	1,670

XI. Required Analyses

A. Executive Order 12291

Under Executive Order 12291, the Agency must judge whether a regulation is "major" and thus subject to the requirement for a Regulatory Impact Analysis. Under E.O. 12291, a major rule is one that is likely to result in: (1) An adverse (cost) impact in the economy of $100 million or more, (2) a major increase in cost or prices to consumers, individual industries, Federal, state, or local government, or geographic region, or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises in domestic or export markets. EPA has determined that today's proposed rule is a major rule for the purposes of E.O. 12291 because the first year cost of the rule is estimated to be $503 million. An RIA entitled, "Regulatory Impact Analysis in Support of Listing Regulated Substances and Thresholds and Mandating Risk Management Programs for Chemical Accident Release Prevention, as Required by Section 112(r) of the Clean Air Act," has been prepared and is available in the docket.

B. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act of 1980, Federal agencies must evaluate the effects of the rule on small entities and examine alternatives that may reduce these effects. EPA has prepared an analysis of the effects on small entities. The analysis employed three measures for assessing the effects of the proposed rule, and the alternatives, on small business: the before-tax cost of compliance as a percentage of firm sales; the after-tax cost of compliance as a percentage of net income; and the percent change in the debt-to-asset ratio. The results indicated that for 90 percent of the small businesses affected, the economic burden for initial costs would be mild. For the remaining 10 percent, the program would impose a significant adverse effect in the first year, as measured by the ratio of after-tax compliance costs to net income. This burden is an upper-bound estimate because, in actuality, many firms are likely to finance compliance in a variety of ways, such as debt, current earnings, and increased prices, rather than finance compliance in one way. Consequently, the impact of compliance costs is likely to be less severe than estimated in the analysis. For subsequent years, the economic impact as measured by the after-tax ratio is estimated to be small for businesses. The impact on small governments also is estimated to be small based on the ratio of compliance costs to revenues. The full regulatory flexibility analysis is included, as Chapter 8, in the RIA, available in the docket.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 1656.1) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA, 401 M St. SW., (PM–223Y), Washington, DC 20460, or by calling (202) 260–2740.

Public reporting burden for this collection of information, which will take place three years after the rule is final, will vary depending on the size and complexity of the facility and the number of substances affected: between 1.25 and 3 hours for the registration form, another .2 to 341.2 hours for the burden to maintain onsite documentation, and a range of between 4.25 and 31.5 hours to prepare and submit a risk management plan. These hours reflect time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, PM–223, U.S. EPA, 401 M St. SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attn: Desk Officer for EPA. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 68

Environmental protection, Accidental release prevention, Chemicals, Chemical accident prevention, Emergency response, Extremely hazardous substances, Hazardous substances, Intergovernmental relations, Process safety management, Risk management.

Dated: October 7, 1993.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, subchapter C, part 68 of the Code of Federal Regulations is proposed to be added to read as follows:

PART 68—ACCIDENTAL RELEASE PREVENTION PROVISIONS

Subpart A—General Provisions

Sec.

68.1 Scope.

Sec.
68.3 Definitions.
68.5 Threshold Determination [Reserved].

Subpart B—Risk Management Plan Requirements

68.10 Applicability.
68.12 Registration.
68.15 Hazard assessment.
68.20 Prevention program purpose.
68.22 Prevention program—management system.
68.24 Prevention program—process hazard analysis.
68.26 Prevention program—process safety information.
68.28 Prevention program—standard operating procedures.
68.30 Prevention program—training.
68.32 Prevention program—maintenance (mechanical integrity).
68.34 Prevention program—pre-startup review.
68.36 Prevention program—management of change.
68.38 Prevention program—safety audits.
68.40 Prevention program—accident investigation.
68.45 Emergency response program.
68.50 Risk management plan.
68.55 Recordkeeping requirements.
68.60 Audits.

Subpart C—List of Regulated Substances and Thresholds for Accidental Release Prevention [Reserved]

Authority: 42 U.S.C. 7412(r) and 7601(a)(1).

Subpart A—General Provisions

§ 68.1 Scope.

This part sets forth requirements for chemical accident prevention steps that must be taken by the owner or operator of stationary sources.

§ 68.3 Definitions.

As used in this part, all terms not defined shall have the meaning given to them by the Clean Air Act (42 U.S.C. 7401 *et seq.*).

Act means the Clean Air Act as amended (42 U.S.C. 7401 *et seq.*).

Administrator means the administrator of the U.S. Environmental Protection Agency.

Analysis of offsite consequences means a qualitative or quantitative analysis of a range of accidental releases, including worst-case releases, to determine offsite effects including potential exposures of affected populations.

Mitigation system means specific equipment, substances or personnel designed or deployed to mitigate an accidental release; examples of mitigation systems include water curtain sprays, foam suppression systems, and emergency response teams.

Offsite means areas beyond the property boundary of the stationary source or areas within the property boundary to which the public has routine and unrestricted access.

Owner or operator means any person who owns, leases, operates, or controls a stationary source.

RMP means the risk management plan required under § 68.50.

SIC means Standard Industrial Classification.

Significant accidental release means any accidental release of a regulated substance that has caused or has the potential to cause offsite consequences such as death, injury, or adverse effects to human health or the environment or to cause the public to shelter-in-place or be evacuated to avoid such consequences.

Worst-case release means the loss of all of the regulated substance from the process in an accidental release that leads to the worst offsite consequences.

§ 68.5 Threshold determination. [Reserved]

Subpart B—Risk Management Program Requirements

§ 68.10 Applicability.

(a) The requirements in this subpart apply to all stationary sources that, after [three years from the date of final rule publication] have a regulated substance present in a process in more than a threshold quantity as determined under § 68.5.

(b) Stationary sources covered by this subpart shall comply with §§ 68.12 through 68.60 no later than [three years after the date of final rule publication] or within three years after the date on which a regulated substance first becomes present in a process in more than a threshold quantity.

§ 68.12 Registration.

(a) By [three years after the publication date of the final rule], or within three years of the date on which a stationary source becomes subject to this subpart, the owner or operator of each stationary source covered by this part shall register with the Administrator.

(b) The registration shall include the following:

(1) The name of the stationary source, its street address, its mailing address, and telephone number;

(2) The names and CAS numbers of all regulated substances that are present at the stationary source in greater than the threshold quantities, and the maximum amount present in a process at any one time (in ranges);

(3) For each regulated substance, the four-digit SIC code(s) that apply to the use of the substance at the stationary source;

(4) The Dun and Bradstreet number of the stationary source;

(5) The name of a contact person; and

(6) The following certification signed by the owner or operator: "The undersigned certifies that, to the best of my knowledge, information, and belief formed after reasonable inquiry, the information submitted is true, accurate, and complete. I certify that I prepared or caused to be prepared a risk management plan that complies with 40 CFR 68.50 [and, when applicable: "and the provisions of 40 CFR 68.60"] and that I submitted or caused to be submitted copies of the risk management plan to each of the entities listed in 40 CFR 68.50(a). [Signature]."

(c) If at any time after the submission of the registration, information in the registration is no longer accurate, the owner or operator shall submit an amended notice within 60 days to the Administrator and implementing agency. After a final determination of necessary revisions under § 68.60(f), the owner or operator shall register the revised risk management plan by the date required in § 68.60(g).

§ 68.15 Hazard assessment.

(a) The purpose of the hazard assessment is to evaluate the impact of significant accidental releases on the public health and environment and to develop a history of such releases.

(b) Hazard assessments shall be conducted for each regulated substance present at the stationary source above the threshold quantity. For each regulated substance, the hazard assessment shall include the following steps:

(1) Determine a worst-case release scenario for the regulated substance at the stationary source;

(2) Identify other more likely significant accidental releases for each process where the regulated substance is present above the threshold quantity, including processes where the substance is manufactured, processed, or used, and where the regulated substance is stored, loaded, or unloaded;

(3) Analyze the offsite consequences of the worst-case release scenario and the other more likely significant accidental release scenarios identified in § 68.15(b)(2); and

(4) Develop a history of accidental releases of the regulated substance.

(c) To determine a worst-case release scenario, the owner or operator shall examine each process handling each regulated substance and assume that all of the regulated substance in the process

is instantaneously released and all mitigation systems fail to minimize the consequences of the release.

(d) The owner or operator shall determine other more likely significant accidental releases such as but not limited to:

(1) Transfer hose failure, excess flow valve or emergency shutoff failure and subsequent loss of piping and shipping container contents (truck or rail);

(2) Process piping failure and loss of contents from both directions from the break; and

(3) Reactor or other process vessel failure where the contents are at temperatures and pressures above ambient conditions. In these situations, passive mitigation systems are assumed to work to minimize the consequences of the release.

(e) For each regulated substance, the offsite consequences of the worst case or more likely significant accidental release scenarios shall be analyzed as follows:

(1) The rate and quantity of substance lost to the air and the duration of the event;

(2) The distance, in all directions, at which exposure to the substance or damage to offsite property or the environment from the release could occur using both worst-case meteorological conditions (i.e., F stability and 1.5 m/sec wind speed) and meteorological conditions most often occurring at the stationary source;

(3) Populations within these distances that could be exposed to the vapor cloud, pressure wave, or debris, depending on wind direction and meteorological conditions; and

(4) Environmental damage that could be expected within these distances, including consideration of sensitive ecosystems, migration routes, vulnerable natural areas, and critical habitats for threatened or endangered species.

(f) The owner or operator shall prepare a five-year history of significant accidental releases and releases with potential for offsite consequences for each regulated substance handled at the stationary source. The history shall list the release date, time, substance and quantity released, the duration of the release, the concentration of the substance released, and any offsite consequences such as deaths, injuries, hospitalizations, medical treatments, evacuations, sheltering in-place, and major off-site environmental impacts such as soil, groundwater, or drinking water contamination, fish kills, and vegetation damage.

(g) The hazard assessment shall be reviewed and updated at least once every five years. If changes in process, management, or any other relevant aspect of the stationary source or its surroundings (e.g. new housing developments or improved emergency response services) might reasonably be expected to make the results of the hazard assessment inaccurate (i.e., if either the worst-case release scenario or the estimate of offsite effects might reasonably be expected to change), the owner or operator shall complete a new or revised hazard assessment within 60 days of such change.

(h) The owner or operator shall maintain the following records documenting the hazard assessment and analysis of offsite consequences:

(1) A description of the worst-case scenario;

(2) A description of the other more likely significant accidental release scenarios identified in § 68.15(b)(2), assumptions used, analyses or worksheets used to derive the accident scenarios, and the rationale for selection of specific scenarios; and

(3) Documentation for how the offsite consequences for each scenario were determined including:

(i) Estimated quantity of substance released, rate of release, and duration of the release;

(ii) Meteorological data used for typical conditions at the stationary source;

(iii) For toxic substances, the concentration used to determine the level of exposure and the data used for that concentration;

(iv) Calculations for determination of the distances downwind to the acute toxicity concentration; and

(v) Data used for estimation of the populations exposed or area damaged.

(i) A summary of the information required under paragraph (h) of this section and a table showing the data for the five-year accident history under paragraph (f) of this section shall be included in the RMP required under § 68.50.

§ 68.20 Prevention program purpose.

The owner or operator of a stationary source having one or more regulated substance above the threshold quantity shall develop and implement an integrated management system to evaluate the hazards present at the stationary source and to find the best ways to control these hazards. The prevention program includes ten required elements that must be tailored to suit the degree of hazards present at the stationary source and the degree of complexity of the stationary source's operations and that should work together under management control to ensure safe operations.

§ 68.22 Prevention program—management system.

(a) The owner or operator of the stationary source shall develop a management system to oversee the implementation of the risk management program elements. The purpose of the management system is to ensure that the elements of the risk management program are integrated and implemented on an ongoing basis and that the responsibility for the overall program and for each element is clear.

(b) As part of the management system, the owner or operator shall identify a single person or position that has the overall responsibility for the development, implementation, and integration of the risk management program requirements.

(c) When responsibility for implementing individual requirements of the risk management program is assigned to persons other than the person designated under paragraph (b) of this section, the names or positions of these people shall be documented and the lines of authority defined through an organization chart or similar document.

§ 68.24 Prevention program—process hazard analysis.

(a) The purpose of the process hazard analysis (hazard evaluation) is to examine, in a systematic, step-by-step way, the equipment, systems, and procedures for handling regulated substances and to identify the mishaps that could occur, analyze the likelihood that mishaps will occur, evaluate the consequences of these mishaps, and analyze the likelihood that safety systems, mitigation systems, and emergency alarms will function properly to eliminate or reduce the consequences of a mishap. A thorough process hazard analysis is the foundation for the remaining elements of the prevention program.

(b) The owner or operator shall perform an initial process hazard analysis on processes covered by this part. The process hazard analysis shall be appropriate to the complexity of the process and shall identify, evaluate, and control the hazards involved in the process. The owner or operator shall determine and document the priority order for conducting process hazard analyses based on a rationale which includes such considerations as the extent of process hazards, offsite consequences, age of the process, and operating history of the process. The process hazard analysis shall be

completed no later than [three years after the date of final rule publication].

(c) Process hazard analyses completed after [Insert date 5 years before the effective date of the final rule] which meet the requirements of this section are acceptable as initial process hazard analyses. These process hazard analyses shall be updated and revalidated, based on their completion date, in accordance with paragraph (h) of this section.

(d) The owner or operator shall use one or more of the following methodologies that are appropriate to determine and evaluate the hazards of the process being analyzed:

(1) What-If;

(2) Checklist;

(3) What-If/Checklist;

(4) Hazard and Operability Study (HAZOP);

(5) Failure Mode and Effects Analysis (FMEA);

(6) Fault Tree Analysis; or

(7) An appropriate equivalent methodology.

(e) The process hazard analysis shall address:

(1) The hazards of the process;

(2) The identification of any previous incident which had a likely potential for significant offsite consequences;

(3) Engineering and administrative controls applicable to the hazards and their interrelationships such as appropriate application of detection methodologies to provide early warning of releases. Acceptable detection methods might include process monitoring and control instrumentation with alarms, and detection hardware such as hydrocarbon sensors;

(4) Consequences of failure of engineering and administrative controls;

(5) Stationary source siting;

(6) Human factors; and

(7) A qualitative evaluation of a range of possible safety and health effects of failure of the controls on public health and the environment.

(f) The process hazard analysis shall be performed by a team with expertise in engineering and process operations, and the team shall include at least one employee who has experience and knowledge specific to the process being evaluated. Also, one member of the team must be knowledgeable in the specific process hazard analysis methodology being used.

(g) The owner or operator shall establish a system to promptly address the team's findings and recommendations; assure that the recommendations are resolved in a timely manner and that the resolution is documented; document what actions are to be taken; complete actions as soon as possible; develop a written schedule of when these actions are to be completed; and communicate the action to operating, maintenance, and other employees whose work assignments are in the process and who are affected by the recommendations or actions.

(h) At least every five (5) years after the completion of the initial process hazard analysis, the process hazard analysis shall be updated and revalidated by a team meeting the requirements in paragraph (f) of this section, to assure that the process hazard analysis is consistent with the current process.

(i) The owner or operator shall retain process hazard analyses and updates or revalidations for each process covered by this section, as well as the documented resolution of recommendations described in paragraph (g) of this section for the life of the process.

(j) Based on the findings and recommendations of the process hazard analysis, the owner or operator shall also investigate, evaluate, and document a plan for, or rationale for not, installing (if not already in place):

(1) Monitors, detectors, sensors, or alarms for early detection of accidental releases;

(2) Secondary containment or control devices such as, but not limited to, flares, scrubbers, quench, surge, or dump tanks, to capture releases; and

(3) Mitigation systems to reduce the downwind consequences of the release.

§ 68.26 Prevention program—process safety information.

(a) The owner or operator shall complete a compilation of written process safety information before conducting any process hazard analysis required in § 68.24. The compilation of written process safety information is to enable the owner or operator and the employees involved in operating the process to identify and understand the hazards posed by those processes involving regulated substances. This process safety information shall include information pertaining to the hazards of the regulated substances used or produced by the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(b) Information pertaining to hazards of the regulated substance in the process. This information shall consist of at least the following:

(1) Toxicity information;

(2) Permissible exposure limits;

(3) Physical data;

(4) Reactivity data;

(5) Corrosivity data;

(6) Thermal and chemical stability data; and

(7) Hazardous effects of inadvertent mixing of different materials that could foreseeably occur.

Note: MSDSs meeting the requirements of 29 CFR 1910.1200(g) may be used to comply with this requirement to the extent they contain the information required by this paragraph.

(c) Information pertaining to the technology of the process. Information concerning the technology of the process shall include at least the following:

(1) A block flow diagram or simplified process flow diagram;

(2) Process chemistry;

(3) Maximum intended inventory;

(4) Safe upper and lower limits for such items as temperatures, pressures, flows, or compositions; and,

(5) An evaluation of the consequences of deviations, including those affecting public health and the environment.

(d) Where the original technological information required by paragraph (c) of this section no longer exists, such information may be developed in conjunction with the process hazard analysis in sufficient detail to support the analysis.

(e) Information pertaining to the equipment in the process. Information pertaining to the equipment in the process shall include:

(1) Materials of construction;

(2) Piping and instrument diagrams (P&ID's);

(3) Electrical classification;

(4) Relief system design and design basis;

(5) Ventilation system design;

(6) Design codes and standards employed;

(7) Material and energy balances for processes built after the effective date of rule; and

(8) Safety systems (e.g., interlocks, detection, or suppression systems).

(f) The owner or operator shall document that equipment complies with recognized and generally accepted good engineering practices.

(g) For existing equipment designed and constructed in accordance with codes, standards, or practices that are no longer in general use, the owner or operator shall determine and document that the equipment is designed, maintained, inspected, tested, and operating in a safe manner.

§ 68.28 Prevention program—standard operating procedures.

(a) The purpose of written standard operating procedures is to document the safe and proper way to operate and maintain processes and equipment, and to handle and store regulated substances at a stationary source. Procedures may

be based on the process hazard analysis (hazard evaluation) information, successful past operating experience, manufacturers' recommendations, and applicable and appropriate codes and standards. The owner or operator shall consider the complexity of the process or stationary source to develop standard procedures.

(b) The owner or operator shall develop and implement written operating procedures that provide clear instructions for safely conducting activities involved in each covered process consistent with the process safety information and shall address at least the following elements:

(1) Steps for each operating phase:

(i) Initial startup;

(ii) Normal operations;

(iii) Temporary operations;

(iv) Emergency shutdown including the conditions under which emergency shutdown is required, and the assignment of shutdown responsibility to qualified operators to assure that emergency shutdown is executed in a safe and timely manner;

(v) Emergency operations;

(vi) Normal shutdown; and

(vii) Startup following a turnaround, or after an emergency shutdown.

(2) Operating limits:

(i) Consequences of deviation; and

(ii) Steps required to correct or avoid deviation.

(3) Safety and health considerations:

(i) Properties of, and hazards presented by, the substances used in the process;

(ii) Precautions necessary to prevent exposure, including engineering controls, administrative controls, and personal protective equipment;

(iii) Control measures to be taken if physical contact or airborne exposure occurs;

(iv) Quality control for raw materials and control of regulated substance inventory levels; and,

(v) Any special or unique hazards.

(4) Safety systems and their functions.

(c) Operating procedures shall be readily accessible to employees who work in or maintain a process.

(d) The operating procedures shall be reviewed as often as necessary to assure that they reflect current operating practice, including changes that result from changes in process chemicals, technology, and equipment, and changes to stationary sources. The owner or operator shall certify annually that these operating procedures are current and accurate.

(e) The owner or operator shall develop and implement safe work practices to provide for the control of hazards during operations involving lockout/tagout; confined space entry; opening process equipment or piping; and control over entrance into a stationary source by maintenance, contractor, laboratory, or other support personnel. These safe work practices shall apply to employees and contractor employees working on a facility.

§ 68.30 Prevention program—training.

(a) The purpose of the training program is to ensure that each employee involved with regulated substances has learned and understands the procedures developed under § 68.28. The owner or operator shall consider the complexity of the procedures, and the complexity of the process or stationary sources when developing training programs.

(b) *Initial training.* (1) Each employee presently operating a process, and each employee before operating a newly assigned process shall be trained in an overview of the process and in the operating procedures as specified in § 68.28. The training shall include emphasis on the specific safety and health standards, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks.

(2) In lieu of initial training for those employees already involved in operating a process on the effective date of this rule, an owner or operator may certify in writing that the employee has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities as specified in the operating procedures.

(c) *Refresher training.* Refresher training shall be provided at least every three years and more often if necessary to each employee involved in operating a covered process to assure that the employee understands and adheres to the current operating procedures in the process. The owner or operator, in consultation with the employees involved in operating the process, shall determine the appropriate frequency of refresher training.

(d) *Training documentation.* The owner or operator shall ascertain that each employee involved in operating a process has received and understood the training required by this section. The owner or operator shall prepare a record which contains the identity of the employee, the date of training, and the means used to verify that the employee understood the training.

(e) The owner or operator shall evaluate the effectiveness of the training program. A schedule for reviewing and revising the program shall be maintained at the stationary source.

§ 68.32 Prevention program—maintenance (mechanical integrity).

(a) The purpose of the maintenance program is to determine and target the specific equipment that is identified through the process hazard analysis (hazard evaluation) or through operating experience as needing regular maintenance because failure of the equipment would lead to a significant accidental release. The owner or operator shall consider the complexity of the process or stationary source in developing the maintenance program.

(b) The owner or operator shall develop a list of equipment and controls the failure of which could result in a significant accidental release. As applicable, the equipment list shall include:

(1) Pressure vessels and storage tanks;

(2) Piping systems (including piping components such as valves);

(3) Relief and vent systems and devices;

(4) Emergency shutdown systems;

(5) Controls (including monitoring devices and sensors, alarms, and interlocks); and,

(6) Pumps.

(c) *Written procedures.* The owner or operator shall establish and implement written procedures to maintain the on-going integrity of process equipment.

(d) *Training for process maintenance activities.* The owner or operator shall train each employee involved in maintaining the on-going integrity of process equipment in an overview of that process and its hazards and in the procedures applicable to the employee's job tasks to assure that the employee can perform the job tasks in a safe manner and shall document the training as required in § 68.30(d).

(e) *Maintenance, inspections, and testing.* For every item of equipment required to be listed under paragraph (b) of this section, the owner or operator shall develop a maintenance program to inspect, test, and maintain the equipment on an appropriate schedule to ensure that the equipment and controls continue to function according to specifications.

(1) Maintenance, inspections, and tests shall be performed on process equipment.

(2) Maintenance, inspection, and testing procedures shall follow recognized and generally accepted good engineering practices.

(3) The frequency of maintenance, inspections, and tests of process equipment shall be consistent with applicable manufacturers' recommendations and good engineering practices, and more frequently if

determined to be necessary by prior operating experience.

(4) The owner or operator shall document each maintenance procedure, inspection, and test that has been performed on process equipment. The documentation shall identify the date of the maintenance/inspection/test; the name of the person who performed the maintenance/inspection/test; the serial number or other identifier of the equipment on which the maintenance, inspection, or test was performed; a description of the maintenance, inspection, and test that is performed; and the results of the inspection or test.

(f) *Equipment deficiencies.* The owner or operator shall correct deficiencies in equipment that are outside acceptable limits (defined in the process safety information in § 68.26(c)(4) and (e)) before further use or in a safe and timely manner when necessary means are taken to assure safe operations.

(g) *Quality assurance.*

(1) In the construction of new plants and equipment, the owner or operator shall assure that equipment as it is fabricated is suitable for the process application for which they will be used.

(2) Appropriate checks and inspections shall be performed to assure that equipment is installed properly and consistent with design specifications and manufacturer's instructions.

(3) The owner or operator shall assure that maintenance materials, spare parts, and equipment are suitable for the process application for which they will be used.

§ 68.34 Prevention program—pre-startup review.

(a) The purpose of the pre-startup review is to ensure that new or modified equipment is ready to properly and safely contain any new or previously handled regulated substance before that substance is introduced into the system. The owner or operator shall consider the complexity of the process or stationary source in developing the pre-startup review.

(b) The owner or operator shall perform a pre-startup safety review for new stationary sources and for modified stationary sources when the modification is significant enough to require a change in the process safety information.

(c) The pre-startup safety review shall confirm that prior to the introduction of regulated substances to a process:

(1) Construction and equipment is in accordance with design specifications;

(2) Safety, operating, maintenance, and emergency procedures are in place and are adequate;

(3) For new stationary sources, a process hazard analysis has been performed and recommendations have been resolved or implemented before startup; and modified stationary sources meet the requirements contained in management of change, § 68.36; and

(4) Training of each employee involved in operating or maintaining a process has been completed and that employees are trained in any new emergency response procedures.

§ 68.36 Prevention program—management of change.

(a) The purpose of a management of change program is to ensure that any alteration of equipment, procedures, substances, or processes are thoroughly analyzed to identify hazards, the consequences of failures, and impacts of the change on existing equipment, procedures, substances, and processes prior to implementation of the change.

(b) For process equipment, devices, or controls, replacement is not a change if the design, materials of construction, and parameters for flow, pressure, and temperature satisfy the design specifications of the device replaced.

(c) The owner or operator shall establish and implement written procedures to manage changes to process chemicals, technology, equipment, and procedures; and changes to stationary sources that affect a covered process.

(d) The procedures shall assure that the following considerations are addressed prior to any change:

(1) The technical basis for the proposed change;

(2) Impact of change on likelihood of a significant accidental release;

(3) Modifications to operating procedures;

(4) Necessary time period for the change; and,

(5) Authorization requirements for the proposed change.

(e) Employees involved in operating a process and maintenance and contract employees whose job tasks will be directly affected by a change in the process shall be informed of and trained in the change prior to the startup of the process or affected part of the process.

(f) If a change covered by this section results in a change in the process safety information required by § 68.26, such information shall be updated accordingly.

(g) If a change covered by this section results in a change in the operating procedures or practices required by § 68.28, such procedures or practices shall be updated accordingly.

§ 68.38 Prevention program—safety audits.

(a) The safety audit consists of a periodic examination of the management systems and programs at the stationary source. The examination shall include a review of the documentation and implementation of the requirements of this subpart. The owner or operator shall consider the complexity of the process and of the process safety management program to develop the safety audit procedures, plans, and timing.

(b) The owners or operators shall certify that they have evaluated compliance with the provisions of this section at least every three years, to verify that the procedures and practices developed under this part are adequate and are being followed.

(c) The safety audit shall be conducted by at least one person knowledgeable in the process.

(d) A report of the findings of the audit shall be developed.

(e) The owner or operator shall promptly determine and document an appropriate response to each of the findings of the audit, and document that deficiencies have been corrected.

(f) The owner or operator shall retain the two most recent safety audit reports, as well as the documented actions in paragraph (e) of this section.

§ 68.40 Prevention program—accident investigation.

(a) The purpose of the accident investigation is to learn the underlying causes of accidents to take steps to prevent them or similar accidental releases from recurring.

(b) The owner or operator shall establish and implement written procedures to investigate each significant accidental release.

(c) The owner or operator shall investigate each significant accidental release.

(d) An accident investigation shall be initiated as promptly as possible, but not later than 48 hours following the significant accidental release.

(e) An accident investigation team shall be established and consist of at least one person knowledgeable in the process involved, including a contract employee if the incident involved work of the contractor, and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the significant accidental release.

(f) A report shall be prepared at the conclusion of the investigation which includes at a minimum:

(1) Date of significant accidental release;

(2) Date investigation began;

(3) A description of the significant accidental release;

(4) The factors that contributed to the significant accidental release, including

its initiating event, and root cause or causes that may have increased the likelihood of the initiating event; and,

(5) Any recommendations resulting from the investigation.

(g) The owner or operator shall establish a system to promptly address and resolve the accident report findings and recommendations. Resolutions and corrective actions shall be documented.

(h) The report shall be reviewed with all affected personnel whose job tasks are relevant to the significant accidental release findings including contract employees where applicable.

(i) Significant accidental release investigation reports shall be retained for five years.

§ 68.45 Emergency response program.

(a) The purpose of the emergency response program is to prepare for response to and mitigation of accidental releases to limit the severity of such releases and their impact on the public health and environment.

(b) The owner or operator of a stationary source shall establish and implement an emergency response plan for responding to and mitigating accidental releases of regulated substances. The plan shall detail the steps all employees shall take in response to accidental releases and shall include:

(1) Evacuation routes or protective actions for employees not directly involved in responding to the release;

(2) Procedures for employees responding to the release, including protective equipment use;

(3) Descriptions of all response and mitigation technologies available at the stationary source; and

(4) Procedures for informing the public and emergency response agencies about releases.

(c) The owner or operator shall develop written procedures for the use of emergency response equipment and for its inspection, testing, and maintenance. The maintenance program for emergency response equipment shall be documented as required in § 68.32(e)(4).

(d) For each regulated substance, the owner or operator shall document the proper first-aid and emergency medical treatment necessary to treat accidental human exposure.

(e) The owner or operator shall train all employees in relevant emergency response procedures and document the training as required under § 68.30(d).

(f) The owner or operator shall conduct drills or exercises to test the plan and evaluate its effectiveness. Each drill or exercise shall be documented in writing and shall include findings of the drill or exercise that indicate aspects of the plan and procedures which need to be revised. Plans shall be revised based on the findings of the drills or exercises. The owner or operator shall document the response to each finding from a drill or exercise. For each finding requiring a change that is implemented, the schedule for implementing the change shall be documented.

(g) Each emergency response plan shall be coordinated with local emergency response plans developed under part 355 of this chapter by the local emergency planning committees and local emergency response agencies. Upon request of the local emergency planning committee, the owner or operator shall promptly provide information to the local emergency planning committee necessary for developing and implementing the community emergency response plan.

(h) The owner and operator shall maintain a copy of the emergency response plan, including descriptions of all mitigation systems in place, at the stationary source.

§ 68.50 Risk management plan.

(a) The owner or operator of a stationary source covered by this part shall submit a risk management plan (report) summarizing the key elements of its risk management program to the implementing agency and shall submit copies to the State Emergency Response Commission, the Local Emergency Planning Committee with jurisdiction for the area where the source is located, and the Chemical Safety and Hazard Investigation Board. Each report submitted by the stationary source shall address all regulated substances present at the stationary source in quantities above the threshold quantity.

(b) The report shall include a copy of the registration form, with updated information to ensure that the registration information is accurate.

(c) The report shall include, for each regulated substance, a summary of the hazard assessment and analysis of offsite consequences and accident history data required by § 68.15(i).

(d) The report shall include, for the stationary source, a description of the major hazards (e.g., equipment failure, human error, natural phenomena, or other factors or a combination of such factors which could lead to a significant accidental release) identified through the process hazard analyses, a description of the consequences of a failure to control for each identified major hazard, a summary of all actions taken or planned to address these hazards, and how significant accidental releases are prevented or mitigated, or the consequences reduced by these actions. The purpose of the summary is to identify major hazards and provide an overview of the prevention program being implemented by the stationary source to prevent significant accidental releases. For each action taken to address a hazard, the report shall include the date on which the action was started (or is scheduled to start) and the actual or scheduled completion date. Where the same actions (e.g., training, certain controls, preventive maintenance programs, improved emergency response plan) address a number of hazards, the description may be organized by actions rather than hazards. If any requirement for the risk management program specified in this subpart is not covered in the summary of actions taken to address hazards, the report shall include a brief description of the stationary source's implementation of the requirement.

(e) The report shall include a summary of the stationary source's emergency response plan. The summary shall include:

(1) The procedures adopted to inform emergency response authorities and the public;

(2) The name or position of the point of contact between the stationary source and the public authorities;

(3) The dates of drills and exercises completed and planned and the results of completed drills; and

(4) A description of coordination with the local emergency planning committee.

(f) The report shall include a description of the management system developed to implement and coordinate the elements of the hazard assessment, prevention program, and emergency response program at the stationary source. The description shall define the person or position at the stationary source that is responsible for the overall implementation and coordination of the risk management program requirements. Where regulated substances are present above their threshold quantities at several locations at the stationary source or where responsibility for implementing individual requirements is delegated to separate groups at the stationary source, an organization chart shall be included to describe the lines of responsibility.

(g) The report shall include a certification by the owner or operator that, to the best of the signer's knowledge, information, and belief formed after reasonable inquiry, the information submitted is true, accurate, and complete.

(h) The report shall be reviewed and updated at least every five years and