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Office of Solid Waste and Emergency Response

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- ☐ A — Signed by AA or DAA
- ☐ B — Signed by Office Director
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2. Originator Information

Name of Contact Person	Mail Code	Office	Telephone Code
Mary Jean Osborne	OS-520	OWPE	475-6720

3. Title

Medical Waste Enforcement Strategy

4 Summary of Directive (include brief statement of purpose)

The purpose of the strategy is to assist Regions and States in implementing the Medical Waste Tracking Program. The strategy provides clarification of the EPA's and States' roles, outlines the tracking & reporting requirements and presents guidelines for prioritizing enforcement

5. Keywords

Medical Waste, Enforcement, Manifest, Infectious Waste, State Priorities

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9. Signature of Lead Office Directives Coordinator	Date
Darlene M Williams	
10. Name and Title of Approving Official	Date

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 1 1989

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: Enforcement Strategy for Medical Waste Tracking Regulation

FROM: J. Winston Porter
Assistant Administrator

TO: Regional Administrators
Regions I - X

This memorandum transmits the final Medical Waste Enforcement Strategy developed by the Office of Waste Programs Enforcement. The purpose of this strategy is to provide Regions and States with guidance in implementing the Medical Waste Tracking Regulation which is scheduled for promulgation in March. The strategy contemplates that the States will be the primary implementors of the demonstration program and encourages Regions and States to innovatively utilize resources to maximize benefits during the limited two-year timeframe of the program. Also provided are a definition of the EPA's and State's roles, clarification of enforcement of the Federal rules, a summary of reporting requirements and a discussion of planned outreach efforts.

I hope that the guidelines presented in the strategy will assist the Regions and States in prioritizing compliance monitoring and enforcement activities. I encourage you to develop innovative methods of promoting compliance with the Medical Waste Tracking Regulation. If you have any questions or concerns, please contact Bruce Diamond, Director, Office of Waste Programs Enforcement.

Attachment

cc: Waste Management Division Directors, Regions I - X
RCRA Branch Chiefs, Regions I - X
Regional Counsels, Regions I - X

U.S. ENVIRONMENTAL PROTECTION AGENCY
Medical Waste Enforcement Strategy

Medical Waste Enforcement Strategy

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Medical Waste Enforcement Strategy

I. Introduction

In October 1988, Congress passed the Medical Waste Tracking Act of 1988 (Act). The Act amends the Solid Waste Disposal Act by creating a new Subtitle J. The Act requires EPA to implement a two-year demonstration program to track certain medical wastes generated in the States of New Jersey, New York, Connecticut, and States contiguous to the Great Lakes (these States are: Pennsylvania, Ohio, Indiana, Illinois, Michigan, Wisconsin and Minnesota). The States participating in the program are classified as "covered" States. Those not participating in the demonstration program would be classified as "non-covered" States. States designated under the Act (e.g., the ten indicated above) may elect to "opt-out" of the program. If so, New York, New Jersey and Connecticut would first have to demonstrate to the Administrator that they have a program in place that is no less stringent than that of the Federal program. The Great Lakes States may opt-out by providing a written notification to the Administrator within 30 days of publication of the Medical Waste Tracking Program in the Federal Register. Additionally, States may elect to participate or "opt-in" to the program; however, their participation is subject to the approval of the Administrator. Once the "opt-in" and "opt-out" period is completed, a list of the States participating in the demonstration program will be published in the Federal Register.

Compliance and enforcement provisions in the Act include the authority to conduct inspections and initiate enforcement actions. EPA (or a duly designated representative) is authorized to conduct inspections and to interview any individual at any establishment where medical waste is being or has been handled. It is important to note that, if medical waste is found in a covered State, it will be presumed to have been generated in that covered State. It will be the responsibility of that waste handler to provide documentation to prove that the waste was not generated in the covered State. EPA may issue administrative orders or commence a civil action and assess or seek civil penalties (in accordance with the "RCRA Civil Penalty Policy") of a maximum of $25,000/day of noncompliance per violation. The United States may seek criminal penalties of a maximum of $50,000 for each day of violation or imprisonment of up to five years. For cases involving knowing endangerment, individuals may be fined up to $250,000 and/or be subject to a prison term not exceeding 15 years. Organizations would be subject to a fine of not more than $1,000,000. Section 11007 of the Act provides that States may conduct inspections and take enforcement actions "to the same extent as the Administrator."

To initiate the two-year demonstration program, EPA is publishing an interim-final rule that will be effective 90 days after publication. Preliminary results from EPA's draft Regulatory Impact Analysis indicate that there are approximately 145,970 generators of medical waste and approximately 1,000 medical waste transporters in the ten States designated under the Act. The Agency has limited information on the number of disposal facilities accepting medical waste from facilities in covered States.

In addition to establishing tracking, segregation, handling, labeling, and marking requirements (discussed in greater detail later in this document), the rule sets certain management standards for medical waste generators, transporters, treaters, and disposers. These management standards apply to medical waste generated in a covered State regardless of where it is transported and ultimately treated or disposed. The management standards require that, prior to transport, regulated medical waste must be segregated into three categories: (1) sharps and residual fluids; (2) fluids greater than 20 ccs; and (3) other regulated medical wastes. Prior to transport, regulated medical wastes must be stored in a non-putrescent state in areas with restricted access, sheds, tractor trailers or other secure containers. In addition to pre-transport and storage standards, there are also decontamination requirements for reusable containers. Any container used for the storage and or transport of regulated medical waste and designated for reuse once emptied, must be rendered free of visible contamination prior to reuse if the container shows visible signs of contamination. The sole distinction between management standards for small generators (those that generate less than 50 pounds/month and ship in quantities of less than 50 pounds per shipment) and large generators, is the need for the latter group to initiate a tracking form.

The purpose of this strategy is to assist Regions and States in implementing the Medical Waste Tracking Program. This strategy provides clarification of the EPA's and States' roles, outlines the tracking and reporting requirements as well as presents guidelines for Regions and States to utilize in prioritizing enforcement activities. The strategy also is intended to encourage Regions and States to utilize resources to maximize benefits during the limited two-year time frame of the demonstration program.

II. Goals

During the limited two-year demonstration program, one of EPA's goals will be to gain experience in dealing with the problem of medical waste, and to incorporate the knowledge and information garnered from the pilot program into the summary

Report to Congress. This will assist in the development of future legislation/regulations regarding medical waste. It will be EPA's goal to encourage States to implement the program by providing the States with significant flexibility to encourage alternative methods of implementation, and to develop innovative approaches to compliance and enforcement. In addition, EPA will develop guidance (e.g., model State programs) to allow States to supplement the tracking rules with other appropriate controls.

Due to the size and diversity of the universe of medical waste handlers, EPA and the States should seek to maximize voluntary compliance through outreach and education efforts. In order to promote compliance, a concerted effort by all levels of government to involve and educate individual citizens (who must become aware of their own waste generation/disposal practices) is necessary. Although the States will be the primary implementors of the program, EPA will provide assistance in establishing a coordinated interstate approach to medical waste tracking. The Federal Medical Waste Tracking Demonstration Program will complement existing State tracking programs.

III. Summary of The Demonstration Program Requirements

This section summarizes the major requirements of the regulation, including the use of the tracking form, information collection and reporting requirements, and pre-transport requirements. It is not intended to provide a discussion of all specific regulatory requirements, or to be used as a substitute for the actual regulatory text.

A. Utilization of Uniform Tracking Form

Section 11003(a)(3) of the Act requires the use of a uniform form for tracking medical waste in the States included in the demonstration program. A copy of the tracking form, and associated instructions for completing it, can be found in Appendix I of the medical waste tracking regulations in 40 CFR Part 259.

The form is comprised of three main sections: one each for generators, transporters, and treatment or disposal facilities. Generators are required to certify that they have properly classified, packaged, marked, and labeled their wastes. Subsequent handlers (transporter(s), and treatment destruction or disposal facilities) must sign and date the form upon receipt of the waste, retain a copy, and return a copy to the generator as evidence of delivery (if the facility treats or disposes of the waste). EPA requires that regulated medical waste be classified as "treated" or "untreated." States may require reporting of additional information on the tracking form (e.g., if State laws are more stringent and cover additional waste categories).

The hierarchy for acquisition of the form (259.52(b)) by generators of medical waste is similar to that for hazardous waste generators (40 CFR 262.21). The generator should take the following steps:

- If the waste is to be shipped out of State to a facility located in another covered State, and that State prints the form, the generator should request a copy from the transporter. The transporter is required to provide a copy to the generator
- If the disposal facility is not in a covered State or it does not print the form, the generator should obtain the form from his own State
- If the form is not available in the generator's State, it must use the Federal form in Appendix I.

B. Reporting Requirements/Information Collection

The Medical Waste Tracking Act and associated regulation (40 CFR Part 259) contain reporting and information collection requirements to ensure compliance with the tracking regulation in the demonstration States and to provide data for requisite Reports to Congress on the success of the program. Reporting requirements contained in the regulations are discussed, followed by a summary of the statutory enforcement-related information requests anticipated by EPA to prepare the requisite Reports to Congress.

The regulation contains four reporting requirements and one notification requirement as follows:

- Section 259.55 - Generator exception reports
- Section 259.62 - On-site incinerator reports
- Section 259.72 - Transporter notification
- Section 259.78 - Transporter semi-annual reports
- Section 259.82 - Tracking form discrepancies

Generator exception reports and tracking form discrepancies must be submitted to both the affected EPA Region and the appropriate State agency. The transporter notifications and semi-annual reports must be sent to EPA Headquarters, with an additional copy of the notification and semi-annual report sent to the appropriate State agency. The on-site incinerator reports must also be submitted to EPA Headquarters. Each reporting requirement is summarized briefly.

Generators

A generator of regulated medical waste that is subject to the tracking requirements must submit an exception report if a

copy of the original form is not received from the designated treatment, destruction, or disposal facility within 45 days. The report must include a legible copy of the original tracking form and a brief letter outlining the generator's efforts to locate the waste.

Incinerators

Generators that incinerate regulated medical waste on site must submit two reports detailing information contained in the facility's operating record six months plus 45 days after the effective date of the tracking regulations, and again eighteen months plus 45 days after the effective date.

The reports must summarize information collected in the operating record during the first and third six-month period after the effective date of the demonstration program. In addition to information on the incineration technology, the reports must include the following waste feed information:

- The approximate total quantity of all regulated medical waste incinerated during the period
- The approximate percentage of total waste incinerated that is regulated medical waste
- Approximate quantity of regulated medical waste received from sources from outside the facility.

Transporters

Transporters of regulated medical waste must submit a one-time notification that includes the transporter's name, address, State permit number (if applicable), EPA Hazardous Waste Identification Number (if applicable), and a statement that the transporter understands the tracking regulation.

Transporters must also submit reports twice annually, on specifically designated dates, detailing the names of generators from which the waste was received, amount and type of waste received from each generator, aggregate amounts of regulated waste transported (detailing treated vs. non-treated), names and addresses of each treatment, destruction or disposal facility to which the wastes were transported, and finally the volume or weight delivered to each facility.

Medical Waste Management Facilities

A tracking form discrepancy report must be submitted by a treatment, destruction or disposal facility that receives regulated medical waste shipments containing:

- Different numbers of containers, total or by category, of regulated medical waste than is indicated on the tracking form

- Waste shipments that have not been packaged as required by Section 259.41

- Or, shipments that are known to contain regulated medical waste generated in a covered State, but have not been accompanied by a tracking form, or where the tracking form is incomplete or unsigned.

The report must be submitted within 15 days from the date the waste was received. A letter describing the discrepancy and the owner/operator's attempts to reconcile the situation, as well as a legible copy of the tracking form, must be submitted to the affected Region and appropriate State agency.

Copies of all reports discussed herein must be maintained for at least three years. They must also be made available to State and EPA personnel in the event of a facility inspection.

C. Pre-Transport Requirements

Regulated medical wastes transported for subsequent management (treatment, destruction or disposal) off site, are subject to pre-transport requirements (40 CFR Part 259, Subpart E) including waste segregation, packaging, labeling and marking.

Segregation (259.40)

Prior to being placed in containers for eventual transport, wastes must be segregated by type as follows:

- Sharps and residual fluids

- Fluids greater than 20 cubic centimeters

- Other regulated medical wastes.

Packaging (259.41)

Before transporting, or offering for transport, regulated medical waste shipments, generators must package waste following standards for each segregated category. All wastes must be packaged in rigid, leak resistant containers. In addition, sharps must be packaged in puncture resistant containers and fluids in break resistant containers. Generators may use any number of containers to meet these packaging requirements, though double packaging will often be necessary.

Labeling (259.44)

Untreated regulated medical wastes must have a water resistant, plastic label affixed to the outside of the packaging that says "Infectious Waste", "Medical Waste" or displays the universal biohazard symbol. If a plastic bag is used for primary (inner) packaging, it must either be red, or display the universal biohazard symbol. Treated wastes are not subject to this requirement.

Marking (259.45)

The packaging (containers) encasing regulated medical waste, must be marked with tags that contain identifying information as specified in the regulations. In addition, each transporter managing a particular waste shipment must individually mark it with a separate tag.

IV. The Relationship Between EPA and The States

Section 11005 of the Medical Waste Tracking Act gives the Administrator authority to issue compliance orders, to assess or seek civil penalties and to seek injunctive relief in United States District Court for past or current violations. It also gives the United States the authority to seek criminal penalties for knowing violations of the Act and knowing endangerment. Section 11004 gives the Administrator, or his representative, authority to conduct inspections and obtain information. In addition to these Federal authorities, States are encouraged to implement State authority as a basis for their enforcement efforts. Section 11007 further provides that States may conduct inspections and take enforcement actions against any person "to the same extent as the Administrator." EPA and State roles are addressed in the following sections.

The State Role

The task of implementing the Medical Waste Tracking Program will lie primarily with the States. States will have the lead for conducting inspections related to, and enforcement of, the medical waste tracking program. Where there has been a violation, States may use applicable State authority to bring an enforcement action. If a State uses its own authority, the involvement of the EPA Regions will be limited. States are a person for the purposes of RCRA, therefore a State may bring a citizen suit under Section 7002 of RCRA against any violator of the Act.

States also may choose to exercise Federal authority under Section 11007 of the Act to enforce the medical waste regulation However, when the President signed the Act into law, he cautioned that "I have also been advised that Section 11007 of this bill,

which authorizes States to take enforcement action against any person 'to the same extent as the Administrator', may raise serious constitutional problems. To the extent that Congress provided for States to prosecute crimes or exercise other executive branch authority, it could be inconsistent with the Appointments Clause of the Constitution." Therefore, States are encouraged to develop comparable State authorities to the Act, and to take action against violators of the Medical Waste Tracking Program under State law or to use the citizen suit provision of RCRA.

If a State nonetheless, elects to enforce under the Federal authority, it is required (by Section 11007(a) of the Act), to notify EPA in writing. This notification must be sent to the Administrator of the EPA and to the EPA Regional Administrator for the Region in which the violation is alleged to have occurred. The notification must include a copy of the complaint. EPA Headquarters will forward a copy of the notification and the complaint or comparable filing to the Assistant Attorney General for the Land and Natural Resources Division of the Department of Justice. Moreover, if a State chooses to pursue enforcement under the Federal authority it is not acting as an agent of the Federal government or the EPA, and State actions should not be viewed as binding EPA as a matter of policy or precedent. Further, if any penalties are obtained in a State initiated enforcement action using Federal authorities, they must go to the Federal Treasury (U.S.C. Title 31 Section 3302(b)).

In response to the new authority provided to the Administrator under Subtitle J, EPA is promulgating, as part of the interim final rule, a regulation that extends the applicability of the Consolidated Rules of Practice (which governs the administrative assessment of civil penalties and the revocation and suspension of permits, 40 CFR Part 22), to administrative enforcement actions taken pursuant to Section 11005 of RCRA. The Consolidated Rules of Practice are applicable only to enforcement actions initiated by the Administrator. If States choose to use Federal authorities, and do not have penalty assessment procedures which satisfy the Act and constitutional requirements for due process, they will need to institute them. In light of the above considerations, States that participate in this two-year demonstration are strongly urged to develop and implement their own authorities to regulate medical waste.

When a covered State receives an exception or discrepancy report that indicates improper handling of shipments of regulated medical waste into an non-covered State, the covered State may either notify the non-covered State directly, or the EPA Regional Administrator of the Region in which the covered State is located. The Regional Administrator will either contact the non-covered State directly, if it is in the same Region, or notify the appropriate EPA Region, who will then contact the non-covered

State. The non-covered State will be given the opportunity and is encouraged to take action. If the non-covered State does not adequately follow up on the tracking exception or discrepancy, EPA will investigate, and if appropriate, take action.

EPA Role

EPA's role in implementing the Act is to ensure compliance by providing information and guidance to the States, to assist States in implementing the objectives of the Act, and to enforce the Act when appropriate. Although the States have a major role in implementing the objectives of the Act, the EPA role includes the following:

- The development of rules, an enforcement strategy, and a penalty guidance document, to provide guidance as to how the objectives of the Act should be implemented and enforced pursuant to State and Federal law
- The development of handbooks, brochures, and other informational materials
- Technical assistance
- The maintenance of data bases, including transporter notifications and reports and incinerator reports
- Handling, as necessary, specific cases involving discrepancies and exceptions in non-covered States
- Evaluation of the success of the program, and submittal of a comprehensive Report to Congress.

EPA's Office of Solid Waste (OSW) will maintain computerized data bases of all transporter notifications and semi-annual reports submitted by transporters. OSW will also maintain all incinerator reports. The EPA Regions should keep a consolidated hard-copy file of all exception and discrepancy reports so that they are easily accessible. States are encouraged to do the same.

EPA anticipates relatively little Federal enforcement action in States that are implementing an effective compliance and inspection program. EPA enforcement initiatives generally will be limited to situations where State enforcement is unsuccessful or inadequate, or to where States solicit Agency intervention. In addition, EPA involvement may be appropriate in the following instances:

- At Federal facilities when the State requests EPA assistance

In following up on regulated medical wastes transported to non-covered States and on Indian lands where there is no comparable State or Indian Tribal statute.

V. Reports to Congress

The Act requires EPA to submit three Reports to Congress: two during the demonstration program, and one summary Report subsequent to completion of the program. The two interim Reports will contain information (on topics listed in Section 11008(a) of the Act) available to the Administrator at the time of submission. The first Report is due nine months after the enactment of Subtitle J, and the second twelve months after the effective date of the medical waste tracking regulation. The summary Report, due three months after the expiration of the demonstration program, will include more detailed and complete information on the same topics identified in Section 11008.

Items 8, 9, and 10 in Section 11008(a) address enforcement-related issues. To comply with the Act, EPA may solicit information from the affected State agencies on:

- Existing State and local controls on the handling, storage, transportation, treatment, and disposal of medical waste, including the enforcement and regulatory supervision thereof

- The appropriateness of using any existing State requirements or requirements contained in Subtitle C as nationwide standards to monitor and control medical waste

- The appropriateness of the penalties provided in Section 11005 for ensuring compliance with the requirements of Subtitle J, including a review of the level of penalties imposed under this Subtitle.

EPA strongly suggests that Regions and States keep accurate, organized information on inspections, violations and enforcement actions under Federal and State authorities, that can be readily retrieved for use in enforcement proceedings and in the evaluation of the effectiveness of the demonstration program. In order to facilitate a smooth transfer of enforcement related information between the States and the Regions as well as the Regions and Headquarters, it is necessary for the Regions to designate a medical waste contact person. EPA will make a concerted effort to minimize the burden on State agencies when soliciting information to complete these Reports to Congress.

VI. Prioritizing Inspection/Enforcement Activities

The medical waste regulation addresses several categories of medical waste generated by a variety of medical facilities/entities. Due to the size and nature (e.g., previously unregulated handlers) of the regulated universe and the limited duration of the tracking program, the Regions and States will have to utilize creative methods for targeting medical waste handlers/facilities for inspections, investigating unresolved exception reports, and other enforcement activities. Some States with medical waste programs currently in place may have information available on the compliance history of medical waste handlers within the State. This information will assist in identifying violators and targeting inspections and enforcement actions. States without existing medical waste programs can utilize the demonstration program to begin developing compliance histories on their medical waste handlers. The required notifications and semi-annual reports from the transporters will provide information on the universe of generators, as well as the types and quantities of medical waste handled. This information may assist Regions and States in identifying problem handlers.

Each covered State may have specific problem areas/regions that may require special enforcement attention. Although the medical waste regulation is required to be implemented throughout the State, resources could be focused on areas with a history of, and the greatest potential for, problems. Because medical waste has created a public health concern, inspections and enforcement could be targeted in areas where there is the most risk to the population (e.g., handlers suspected of contaminating public beaches). In addition to focusing on specific problem areas, promoting voluntary compliance through outreach and education is critical to the success of the demonstration tracking program, especially due to the fact that many medical waste handlers have not previously been subject to RCRA.

VII. Innovative Compliance Monitoring and Enforcement

Due to the short timeframe for implementing the tracking program, it may be useful for the Regions and States to devise innovative methods of inspection and creative settlement agreements. Hospital accreditation boards or self-auditing programs for medical waste handlers may provide mechanisms for promoting and assisting in evaluating compliance with the medical waste regulation and management standards. Cooperative efforts could be initiated with local health and transportation departments that already conduct inspections at medical facilities. In addition, major medical waste handlers could be encouraged to develop their own compliance audit plans.

For example, creative settlements, in addition to collecting penalties pursuant to EPA's RCRA Civil Penalty Policy or under

appropriate State authority, could require violators (especially major medical waste handlers) to develop in-house training programs on the proper handling of medical waste or cleanup measures for potentially affected locations. Outside the context of settlement agreements, publicizing well-chosen cases of serious non-compliance in the local newspapers or in television broadcasts would be another technique that could be used to encourage compliance.

Informal enforcement mechanisms are an integral component of an effective comprehensive compliance monitoring and enforcement program. Less resource-intensive, informal enforcement actions may be warranted in many cases, due to the newness of the program, the large size of the regulated universe and the diverse nature of the medical community. Some of the more commonly employed informal enforcement techniques include warning letters and notices of violation.

Formal enforcement actions consist primarily of administrative compliance orders and penalty assessments or judicial actions; however, there may be additional enforcement mechanisms available under State authorities. Formal enforcement action may be appropriate for serious types of violations of the medical waste tracking regulation such as:

- Transporting, or delivering/offering for transportation, regulated medical waste without a tracking form
- Improper labeling of the regulated medical waste
- Failure of the medical waste transporter to comply with the one-time notification to EPA
- Failure of generators to file exception reports or owner/operators of TSDs to file discrepancy reports.

In addition, it may be appropriate to pursue criminal enforcement actions in cases where generators have falsified information on the tracking form. Criminal actions may also be appropriate against generators who fail to use the form.

VIII. Outreach/Education

EPA's OSW will develop several written communication materials that describe the requirements of the medical waste tracking program. In February 1989, there will be a general public brochure available that summarizes the provisions of the demonstration program. In April 1989, OSW plans to publish a generator booklet detailing the tracking program requirements from the generator's perspective. Transporter and disposal facility brochures describing their respective responsibilities will also be published and distributed. In addition, posters

targeted to the non-regulated community (e.g., diabetics) on the safe handling and disposal of medical waste, will be posted in appropriate public places (e.g., pharmacies). OSW is also developing a bibliography of abstracts on infectious waste studies, articles and other literature as well as an information clearinghouse on medical wastes. OSW will determine the distribution mechanism of these documents once they are finalized.

Some States have already undertaken outreach and educational efforts. For example, the States of New York and New Jersey have developed a 14-point action plan, which includes provisions for waste minimization, public education and guidance on handling medical waste mismanagement incidents. Both States have also conducted meetings and briefings with hospital associations.

IX. Federal Facilities

Section 11006 of the Act waives the sovereign immunity of Federal facilities from regulatory requirements contained in 40 CFR Part 259 as well as all local and State medical waste requirements, if they are located in a covered State. The Act provides that Federal facilities may be exempted from the regulation when deemed in the national interest by the President. These exemptions will likely be rare, must be renewed each fiscal budgetary year, and must be reported to Congress.

States will have primary enforcement responsibility at Federal facilities, as with all facilities within their jurisdiction. EPA will assist the States in pursuing compliance of the medical waste tracking regulation at non-compliant Federal facilities where requested by the affected State agency or as otherwise necessary.

X. Indian Lands

EPA is the only body with authority to enforce a Federal Act on lands held in trust for, or under the jurisdiction of, a Federally-recognized Indian Tribe. Where a Tribe has its own law to track medical waste, EPA encourages the Tribe to take enforcement action under Tribal law.

When a covered State receives an exception or discrepancy report that indicates that medical waste has entered Indian land from a covered State, that State should notify the affected EPA Regional Administrator and the head of the Tribal government. EPA will work cooperatively with Indian Tribes to ensure coordination and to avoid duplication of effort in inspections and enforcement actions.

XI. Conclusion

The goals of the Medical Waste Tracking Demonstration Program will be achieved through promoting compliance with the regulation. EPA's compliance and enforcement strategy will rely primarily on promoting compliance through the development and support of State compliance and enforcement programs. EPA Regions will work with States to identify and resolve State-specific enforcement issues and assist States in developing programs. EPA will provide assistance and tools to help the States. The tools will include providing information as well as developing and sharing effective methods to promote compliance. EPA recognizes that voluntary compliance will not be achieved in all cases. State and local enforcement actions are a necessary foundation for an effective compliance effort. In addition, there may be instances where Federal enforcement presence will be appropriate.