

The Necessity for Environmental Auditing of Hospitals

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A hospital management team's confidence that the hospital's balance sheet fairly states the financial position of the hospital is enhanced if the financial statement has been audited by an independent certified public accountant. The hospital management team should have similar confidence that the hospital is operating in compliance with federal and state environmental regulations if the hospital has undergone a periodic review of the hospital's environmental operations. While independent financial audits are part of a hospital's business cycle, environmental audits are becoming more common at hospitals because their value is being affirmed in practice.

EPA Has Increased its Level of Scrutiny of Hospitals

The U.S. Environmental Protection Agency (EPA) has, for much of the past decade, raised its level of scrutiny of and enforcement against hospitals. Hospital preparedness for the EPA inspection or inquiry is enhanced where the hospital has in place an audit protocol, a practice of conducting environmental audits. These audits, like financial internal control audits, detect systemic weaknesses in the hospital's procedures which presently may have led to no problems but are at risk to lead to a troubled future. Environmental audits provide the hospital—which shores up internal control weaknesses to guard against fraud—with opportunity to improve procedures, conduct employee training or acquire updated equipment to lessen the risk of an environmental violation.

Hospitals have commanded more of EPA's attention in recent years because of the nature of hospital operations, the materials they handle and the waste they generate. Laboratories, power plants and vehicle maintenance shops, and other facilities which are higher risk for environmental violations,¹ are common on hospital campuses. EPA has listed areas posing compliance challenges for hospitals: "improper handling and disposal of hazardous waste materials; boilers and furnaces that are not in compliance with clean air regulations; inadequate monitoring of underground storage tanks; sewage treatment facilities that are not operating properly; and improper abatement of lead-based paint and asbestos."²

EPA's Regions 2 and 4 explain that their emphasis on hospital compliance and enforcement is due to hospitals' disproportionate use of materials and generation of wastes relating to the presence of "mercury, dioxin, and other persistent bioaccumulative toxic chemicals in the environment."³ Any manufacturer or business which generates hazardous wastes is obviously a higher risk environment for non-compliance. Hospitals generate a wide array of hazardous wastes from chemotherapy, antineoplastic chemicals, solvents, formaldehyde, photographic chemicals, radionuclides, and waste anesthetic gases.⁴ Hospitals that also serve as research facilities typically generate more hazardous wastes.⁵ Hospitals are a major generator of solid wastes destined for disposal at municipal solid waste landfills.⁶ EPA has surmised that hospitals have been much slower than the manufacturing sector to achieve environmental compliance and implement pollution minimization.⁷ Several state environmental regulatory agencies have devoted significant resources toward violations by hospitals.⁸

EPA has undertaken pollution prevention goals for the health care industry, including the elimination or reduction of mercury, bioaccumulative chemicals and solid waste.⁹ In September 2009, EPA announced new limits on infectious waste incinerators to reduce emissions of acid gases, nitrogen oxides and certain metals.¹⁰ Hospitals' operation of medical waste incinerators has been a particular area of enforcement by EPA.¹¹ EPA Region 3¹² has brought a number of enforcement actions against hospitals for asbestos emissions and violations of underground storage tank rules.¹³

Hospitals Are Increasing Their Use of Environmental Audits

Due in large part to the EPA's emphasis on enforcement against hospitals,¹⁴ more hospitals have volunteered to conduct environmental audits and to disclose to EPA the discovered violations.¹⁵ Hospitals are entering into audit agreements with EPA, conducting comprehensive environmental audits, reporting violations to EPA and devoting resources to timely correct the discovered areas of non-compliance.¹⁶

Pursuant to EPA's Audit Policy,¹⁷ any hospital or other entity may enter into an audit agreement with EPA, committing on the front end that environmental violations discovered during the audit will be disclosed to EPA. Under the Audit Policy, the disclosing entity must complete corrective action within 60 days of discovery of the violation. By entering into an audit agreement, the hospital may negotiate extensions of this corrective action period with EPA. This extended correction period, of course, would not apply to violations posing imminent and substantial danger to human health or the environment, which must be

corrected as soon as possible. As of December 2008, nearly 15,000 companies had made voluntary disclosures to EPA and took corrective action under the Policy.¹⁸

Hospitals undertaking an environmental audit are conducting a type of internal investigation to assess the hospital's compliance with the broad scope of environmental regulations which govern health care entities. The best practice, in most situations, is for an outside environmental consultant to conduct the audit. This practice gives the hospital the best opportunity for an independent review of the hospital's environmental compliance. An outside environmental consultant can avoid bias of an inside auditor who may rationalize that the hospital's way, though technically non-compliant, is the only practical way. The outside consultant can evade institutional resistance during the audit and can influence the changes necessary after the audit.¹⁹

EPA and some state environmental agencies publish protocols for environmental audits.²⁰ The International Standards Organization 14001 standard includes a protocol for conducting an environmental audit. EPA's Region 3 has developed a list of questions for a hospital to assess its environmental compliance and to discover areas of non-compliance.²¹ A comprehensive environmental audit by a hospital commonly encompasses a review of the hospital's compliance with the requirements of each major federal environmental program which regulate, collectively, air, water, pesticides, solid waste, hazardous waste, hazardous substances and chemicals, environmental response, emergency planning, toxic substances and the community's right-to-know.

Environmental Auditing Reduces the Risk That Non-Compliance Will Persist Undetected

Audits allow the hospital to avoid environmental problems which are developing, unnoticed by hospital management. The longer non-compliance persists, the more expensive it can become to correct. Remedial measures usually demand measures more disruptive to the hospital's operations the longer the noncompliance persists.

An environmental audit allows the hospital to assess the state of its environmental management systems. An environmental audit provides hospital management with a concentrated opportunity to evaluate whether the facility has a system in place to achieve and maintain compliance while detecting and correcting non-compliance.²² The audit can unify hospital administration and environmental managers toward the common goal of determining whether there are systemic causes for non-compliance, facility-wide. Hospital personnel with various environmental responsibilities, during and after an environmental audit, can collectively assess whether violations and non-compliance are the result of

inadequate employee training, obsolete equipment, unmaintained machinery, problems with sampling protocols or monitoring.²³ The audit allows the entity to refine its procedures to reduce the risk of reoccurrence.²⁴

The audit forces hospital management to regard the hospital's various units as a whole, which is necessary in several regulatory contexts. For example, whether a hospital is required to hold certain air permits may depend on the level of emissions from facilities such as boilers, generators or backup generators used in the event of power loss.²⁵ The environmental audit may detect the need for a system wide air emissions inventory to determine whether thresholds site wide have been neared or reached, requiring additional permitting. The hospital's air permit will require the hospital to maintain records of maintenance checks and readiness testing on air emissions equipment.

The hospital will be subject to emergency planning and notification requirements if it has an "extremely hazardous substance" on site in excess of the regulatory "threshold planning quantity."²⁶ The audit may provide a fresh assessment of the hospital's compliance with these requirements.

Chemicals used across a hospital campus can, collectively, trigger reporting or permitting requirements, such as the need for a facility wide Risk Management Plan.²⁷ Chemicals may be located in laundries, pharmacies, utilities, laboratories and other locations. Whether the hospital or an off site facility needs a Spill Prevention, Control and Countermeasure Plan, depends on whether, site wide, the facility has oil storage capacity over certain thresholds.²⁸ The environmental audit provides an excellent opportunity for the hospital to determine or affirm whether, collectively, the hospital meets these thresholds for regulatory compliance.

An aging hospital's physical plant may raise certain compliance issues during the audit. For example, hospital buildings may contain lead paint if the buildings were renovated or repaired prior to 1978. Hospital buildings constructed or renovated between 1950 and 1978 buildings may have caulk containing PCBs, requiring abatement.²⁹

Hospitals often have off campus facilities, such as clinics, laboratories, and physicians' offices. It is possible that off site operations have not been as closely watched since hospital environmental managers will have more day to day contact with the on campus operations. The environmental audit allows a fresh look at environmental risks which may exist off campus. Third party contractors may have taken on waste management or hazardous substances handling for the hospital. The environmental audit allows the hospital to interact

with these third party contractors to determine whether their employees are properly trained and are maintaining proper record keeping.

Hospitals may lease unused grounds or buildings to businesses totally unrelated to the operation of the hospital. The environmental audit provides opportunity for the hospital to have its consultant do a Phase I Environmental Site Assessment-type walk through of the leased premises to observe whether there are any apparent environmental compliance issues to be addressed. Environmental statutes and regulations hold owners liable for the environmental defaults of their site lessees.³⁰

Spills or discharges of hazardous or harmful substances may have occurred during the year and may have gone unreported. The environmental audit allows the hospital to exercise due diligence by sending consultants out to question operations managers about unusual events to evaluate whether any reporting requirements have been violated and whether the release was due to procedural weaknesses, poor personnel training or other systemic problems that can be corrected.

Use of EPA's Audit Policy Can Reduce Exposure to Civil Penalties

A major incentive for a hospital or company to engage in an environmental audit is to have opportunity to discover and report violations of environmental regulations and minimize or eliminate penalty exposure, utilizing EPA's Audit Policy. Two main principles govern EPA's calculations of civil penalties assessed for environmental violations. First, EPA attempts to recover from the environmental violator the economic benefit enjoyed by the violator due to the non-compliance. Second, EPA calculates the penalty, taking into account the gravity or egregiousness of the violator's behavior. EPA's Audit Policy allows EPA to waive "gravity based" penalties if the audited entity meets nine conditions.

Under the Audit Policy, EPA retains discretion to collect penalties based on the economic windfall enjoyed by the audited entity as a result of its non-compliance. However, EPA may waive the economic based penalties where the economic benefit is insignificant.³¹ Often, the EPA determines that an audited hospital enjoyed no economic benefit from the environmental non-compliance.³² Moreover, an argument may be made that the economic benefit portion of the penalty should be waived by EPA because a purpose of this part of the penalty is to protect compliant companies from competitive disadvantages. It could be argued that this interest is not as important in the context of health care and particularly where non-profit hospitals are involved. In any event, the offending hospital should be prepared to make an argument to EPA that the posture of operating out of environmental

compliance did not provide a competitive advantage against hospitals maintaining compliance.³³

Environmental Audits Can Reduce Penalty Exposure If Certain Conditions Are Met

The hospital or other audited entity qualifies for elimination of all gravity based entities if it meets nine conditions. Condition one is that the environmental violation was discovered during an environmental audit or through operation of the entity's "compliance management program," which is the system the entity has put in place to train employees to prevent, detect, report and correct instances of environmental non-compliance.³⁴ EPA will require the reporting entity to be committed to a policy of conducting periodic audits. An acceptable practice is for the entity to conduct environmental audits of certain facilities or media annually on a pace whereby after every third year, all media or facilities have been audited.

Condition two of the Audit Policy is that the environmental violation must have been detected "voluntarily," meaning that the discovery was not made as part of periodic monitoring, sampling or auditing which the entity is required to conduct by permit, law or by enforcement order.³⁵

Condition three of the Audit Policy requires that the environmental violation was reported to EPA within 21 days of discovery. The audited entity may be able to negotiate with EPA to relax this deadline.³⁶ EPA is particularly amenable to a negotiated extension of this reporting deadline where, as is commonly the case with hospitals, the reporting entity has multiple locations. EPA will set an extended reporting deadline as part of an audit agreement with the reporting entity.³⁷

The fourth condition for the elimination of gravity based penalties is that the audited entity discover the violation "independently," before the government likely would have discovered the violation as part of an ongoing violation or as the result of a tip from a third party. For example, if a private citizen had reported to EPA that the hospital was engaged in an ongoing air emissions violation through the operation of a boiler, the hospital could not cloak the discovery in an environmental audit and receive the preferential penalty treatment under the EPA Audit Policy.³⁸ This condition will not necessarily prohibit a multi-campus hospital from earning penalty reduction from EPA where the independent discovery condition cannot be satisfied as to one of multiple locations.

Condition five requires the audited entity to remedy harm and correct the violation within 60 days of discovery.³⁹ This sixty day corrective action window can be extended by negotiation with EPA on a violation by violation basis.⁴⁰

Condition six of the Audit Policy requires that the audited entity commit in writing to and take steps to prevent a repeat violation.⁴¹ If the hospital's audit uncovers environmental violations and the audit report documents those violations, if corrective action is not taken, the report itself can be used as proof to establish a knowing or criminal violation by the audited entity.

Under condition seven, repeat violations do not qualify for preferential penalty policy treatment. If the same or a similar violation has occurred at the reporting entity within three years, the violation is a repeat violation. If the audited entity has multiple facilities, the violation will not qualify for penalty relief if the violation was part of a pattern of violations at one or more of the facilities within the past five years.⁴²

Condition eight requires that the violation not be one which poses "serious actual harm to the environment or which may have presented an imminent and substantial endangerment to public health or the environment."⁴³

Condition nine is that the audited entity must cooperate with EPA's request for information regarding the environmental violations in order to allow EPA to "determine the applicability" of the audit policy to the violation.⁴⁴ The audit report itself will, in most cases, remain confidential. EPA will only request a copy of the report if the report is needed for EPA's determination of the applicability of the Policy to the violation and the information is not available from other sources.⁴⁵

The Hospital May Structure the Environmental Audit to Preserve Confidentiality of the Audit Report

A hospital may conduct an environmental audit while preserving some degree of confidentiality over the findings from the audit. EPA's Audit Policy regards an audited entity as cooperative without requiring disclosure of the audit report itself. EPA will not routinely request a copy of the audit report.⁴⁶ EPA requires disclosure of information sufficient for the Agency to assess whether the reporting hospital has met the criteria of the Audit Policy.⁴⁷ Therefore, the audit report may be used as an internal document. The confidentiality of the audit report, under the protection of the attorney-client privilege and work product doctrine

is enhanced if the outside consultant has been retained by counsel to inform outside counsel's legal advice to the hospital.⁴⁸

EPA will respect the confidentiality of the audit report itself, requiring disclosure of the violations without necessarily disclosing circumstances surrounding the violations. EPA's follow-up may require disclosures of some of these facts, without disclosure of the audit report itself. However, if EPA has information of an environmental violation from a source independent of the self-disclosure under the Audit Policy, the EPA may request the Audit Report "to establish the extent and nature of the violation and the degree of culpability."⁴⁹ Moreover, assuming there is no criminal investigation, the hospital may cooperate with the EPA's audit program without providing EPA with unlimited access to the entity's employees.⁵⁰ In the event of a criminal investigation, EPA requires broader access to documents, employees and to persons involved in the audit itself.⁵¹

The environmental audit may uncover evidence of an environmental crime. In the event that a criminal investigation is opened by the government, the audit report will be subject to a grand jury subpoena. Hospital management may meet efforts by prosecutors, or even civil litigants, to compel production of the audit report with a claim of the self audit or self-critical analysis privilege, first found applicable to communications in hospital staff meetings. At least one court has found this privilege applicable to environmental audits. The self audit or self critical analysis privilege was recognized to promote the public's interest in having health care providers engage in candid evaluation of health care quality. Similar interests would appear to be at issue with respect to an entity's auditing of its compliance with environmental regulations.⁵²

While the audit report most likely will remain confidential, the violations discovered during the audit are disclosed to EPA and are discoverable by the public. This, of course raises the risk that the environmental audit itself can lead to a lawsuit brought by a private citizen. The federal environmental statutes include "citizen suit" provisions, providing standing to members of the public to sue for environmental violations. However, citizen suits may only be brought where there are "ongoing" violations. Therefore, violations discovered during the environmental audit will be, under the Audit Policy, corrected and remediated within a short time frame, making a citizen suit difficult to sustain.⁵³ Therefore, a Clean Water Act violation discovered by an environmental audit and later corrected cannot be the basis of a sustainable citizen's suit. Nevertheless, the environmental audit may uncover environmental non-compliance which becomes the basis of a common law suit. Hospital management should be aware that the audit report itself may be subject to civil discovery.⁵⁴

About half of the states have statutorily created a privilege barring the use of an environmental audit report in civil proceedings.⁵⁵ This privilege addresses a downside of environmental self audits, which is that they create documentation of environmental non-compliance which may be used by civil litigants as the basis for a personal injury lawsuit. EPA's Audit Policy states EPA's opposition to these state-recognized audit privileges and its intent to undermine them.⁵⁶

Many states statutorily encourage businesses to self-audit and report environmental violations by offering to them penalty reduction or penalty immunity.⁵⁷ A few states go so far as to offer some form of shield against civil suits, or immunity from prosecution.⁵⁸ The states, in almost all cases, like EPA, require that the violation be voluntarily disclosed and that remedial action be taken promptly in order for the violator to qualify for the statutory immunity.⁵⁹ EPA is not, of course, bound by state immunity laws. Penalty mitigation or elimination on the federal level must be earned on the EPA's terms.

An Environmental Audit May Reduce Exposure to Lawsuits

Environmental audits, if handled properly, can assist the hospital in avoiding and minimizing liability from tort lawsuits. The environmental audit allows the hospital to detect and correct environmental non-compliance which, if detected otherwise, can lead to costly litigation. Juries are instructed by courts to assess whether the defendant "knew or should have known" of the violating condition. The environmental audit is a periodic self-assessment of whether the audited hospital meets this legal standard. The audit allows the hospital to take immediate remedial measures designed to restrict exposure or access to contaminated areas.⁶⁰

Environmental Auditing May Reduce the Number of Inspections by EPA

Environmental auditing may lead to fewer inspections of hospital operations by EPA. For several years, EPA has conducted inspections of hospitals, focusing on the determination of the hospital's compliance with regulations applicable to hazardous waste, underground and above ground storage tanks, wastewater discharges, stormwater discharges and air emissions.⁶¹ EPA inspections of hospitals have uncovered pharmaceutical and chemical waste handling violations.⁶² A hospital may negotiate, as part of an audit agreement, EPA's designation of the facility as "low priority" for compliance inspections.⁶³ However, EPA would give higher priority to these inspections in the event of receipt of a citizen's complaint or information indicating a possible criminal violation or one involving a substantial threat to public health or the environment.⁶⁴

Environmental Auditing May Reduce Exposure to Criminal Prosecution

An environmental audit can reduce the risk that the audited entity will be criminally prosecuted for environmental violations discovered during the audit. According to the Audit Policy, EPA will not recommend criminal prosecution to the Department of Justice if the audited entity meets conditions two through nine of the Audit Policy, as long as its self-policing, discovery and disclosure were conducted in good faith and the entity adopts a systematic approach to preventing recurrence of the violation.⁶⁵ EPA's position that it will not recommend criminal prosecution does not apply "where corporate officials are consciously involved in or willfully blind to violations, or condone noncompliance."⁶⁶ Moreover, EPA's offer is not applicable to environmental violations "which may pose imminent and substantial endangerment to human health or the environment...."⁶⁷

It is important to appreciate that the Policy does not immunize the audited entity from criminal prosecution. EPA expressly reserves the right, in the Audit Policy, to refer the violator for criminal prosecution. Moreover, while the Policy creates a presumption that the audited entity will not be referred by EPA to DOJ for prosecution,⁶⁸ it provides no such presumption for the entity's officers, directors, employees or other individuals.⁶⁹ Prosecutors often pursue indictment of upper level corporate officers and environmental managers who are perceived to have been in a position to avoid the non-compliance.⁷⁰

In addition to EPA's commitment to not recommend the audited entity for prosecution, the Department of Justice's policy is to encourage self-auditing and voluntary disclosure by regulated entities by offering not to prosecute organizations with operative self-auditing protocols in place.⁷¹ The DOJ's Policy qualifies that this informal immunity is applicable if the company's audit program functions to prevent repeat violations.

Environmental Auditing can Protect and Enhance the Public's Perception of a Hospital

A hospital's regular practice of conducting environmental audits can improve the market's and public's perception of the hospital. A practice of regular environmental audits enhances the hospital's marketability. The performance of environmental audits allows the audited entity to represent itself to potential buyers as an environmentally responsible corporate citizen.⁷² Moreover, the environmental audit provides the hospital with a better opportunity to plan for and minimize negative publicity flowing from violations. Publicity associated with environmental audits can be positive and negative. The hospital should receive positive publicity from entering into an environmental audit agreement with EPA. However, the hospital must consider the possibility of eventual negative publicity from environmental

non-compliance discovered during the audit.⁷³ EPA's practice is to provide public notice of compliance agreements entered into under the Audit Policy. EPA places copies of settlements in its Audit Policy Docket.⁷⁴ But most environmental violations discovered in a hospital's environmental audit are hardly newsworthy.

Where environmental violations at a hospital are newsworthy, it is better for them to become public in the context of a hospital having been proactive to seek out the prospect of environmental non-compliance. If the violation is discovered by the federal or state regulator during a site inspection, the regulator may choose to expose the hospital as an example of an irresponsible corporate citizen. However, if the hospital has self-investigated the degree of its environmental compliance, it will have opportunity to prepare its message to the public as to what has been discovered, how it was discovered and what the hospital will do to get remedial measures in place.⁷⁵

Conclusion

Obviously, and for various reasons, financial audits are more engrained in the yearly cycle of a hospital's operations than are environmental audits. Environmental auditing will follow in due time to be a non-negotiable practice in the hospital's business year. The benefits of environmental auditing, particularly for hospitals, with their operational complexities, immense campuses and higher volume generation of solid wastes, wastewater, and hazardous wastes, will necessitate the regularity of these reviews for responsible management.

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¹ Martha Kessler, *Enforcement: Yale-New Haven Hospital Accepts EPA Plan for Comprehensive Environmental Audit*, 237 DEN A-8 (Dec. 10, 2004) (quoting Robert W. Varney, EPA Region I Administrator).

² See "Information on Hospitals," available at www.epa.gov/Region3/compliance_assistance/hospitals.htm.

³ Region 2 is composed of New Jersey, New York, Puerto Rico and the U. S. Virgin Islands. Region 4 includes Alabama, Florida, Georgia, Kentucky, North Carolina, Mississippi, South Carolina and Tennessee. Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005).

- ⁴ *Id.* (quoting EPA Region II and IV websites)
- ⁵ See Hazardous Waste Management Regulations, 40 C.F.R. 260–270.
- ⁶ Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005).
- ⁷ *Id.*
- ⁸ *Id.* (citing enforcement actions against hospitals in New Jersey, Pennsylvania, Kansas, Nebraska, Missouri, Iowa, Idaho, Connecticut, Michigan, Texas and the District of Columbia).
- ⁹ *Id.*
- ¹⁰ See "EPA Tightens Air Emissions for Hospital, Medical, and Infectious Waste Incinerators," available at www.hercenter.org.
- ¹¹ *Id.*
- ¹² Region 3 covers Delaware, Maryland, Pennsylvania, West Virginia, Virginia, and the District of Columbia.
- ¹³ Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005).
- ¹⁴ In 2004, Region 1 of EPA notified hospitals in New England that EPA would "step up" its enforcement at health care facilities. Martha Kessler, *Enforcement: Health Care System in New England Agrees to Undertake Voluntary Environmental Audit*, 29 Chem. 571 (May 30, 2005). Also in 2004, Region 2 increased inspections of hospitals and other health care institutions. Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005) (listing several civil penalty settlements and proceedings against hospitals in New England).
- ¹⁵ Kessler, *supra* note 14, (discussing Caritas Christi Health Care's decision to undertake an environmental audit at 66 of its facilities in New Hampshire and Massachusetts). New-York Presbyterian, the largest hospital in New York City, opted to enter into an audit agreement with EPA as part of the agency's Healthcare Compliance Initiative. See Press Release, "EPA Agrees to New York-Presbyterian Hospital Environmental Self-Audit" (Nov. 17, 2003).
- ¹⁶ See "Audit Agreements," available at www.epa.gov/region2/capp/cip/agreeex (listing audit agreements entered into between EPA Region 2 and several hospitals, including Maimonides Medical Center (the third largest hospital in the United States at that time) (Sept. 30, 2003); St. Barnabas Hospital (the 15th largest hospital in New York State) (Oct. 6, 2003); and Winthrop University Hospital (the first hospital in the country to enter into an audit agreement with EPA) (May 2003).
- ¹⁷ 65 Fed. Reg. 19618–19627, *Incentives for Self-Policing: Discovery, Disclosure, Correction & Prevention of Violations* (Apr. 11, 2000).
- ¹⁸ Ridgway M. Hall, Jr., "The Evolution and New Directions in Environmental Auditing & Compliance Management," Natural Resources & Environment (ABA Section of Environment, Energy, and Resources) (Fall 2009). The largest settlement to date under the Audit Policy was recently entered into by Invista, which audited twelve facilities it acquired from DuPont. The audit and settlement with EPA resulted in Invista paying a civil penalty of \$1.7 million and agreeing to invest about \$500 million to take corrective actions. The audits revealed nearly 70 violations of water, air, hazardous waste,

emergency planning and preparedness, and pesticide regulations. DOJ-EPA Press Release, *"United States Announces Largest Settlement Under EPA's Audit Policy,"* (April 13, 2009).

¹⁹ Daniel Riesel, *Environmental Enforcement-Civil & Criminal* (2009) [hereinafter "Riesel"] at 8-26, 8-27 (citing Fredmon, *Practical Guide to Environmental Management*, 134 (6th ed. 1995)).

²⁰ EPA's website contains the following protocols particularly relevant to hospitals: *Protocol for Conducting Environmental Compliance Audits and the Comprehensive Environmental Response, Compensation & Liability Act* (Dec. 1, 1998); *Protocol for Conducting Environmental Compliance Audits under the Emergency Planning & Community Right-to-Know Act & CERCLA Section 103* (Mar. 1, 2001); *Protocol for Conducting Environmental Compliance, Audits of Hazardous Waste Generators under the Resource Conservation & Recovery Act* (Oct. 1, 1998). The "EPA New England-Hospital Environmental Assessment Template" (April 2004), is available on the website for EPA-New England Region. This template has a checklist to test hospital compliance with the Resource Conservation & Recovery Act, regulations for the handling of universal waste such as batteries, pesticides, lamps and thermostats, requirements for Spill Prevention Control Countermeasure Plans, underground storage tank regulations, Community Right to Know requirements, Clean Air Act regulations, the Federal Insecticide, Fungicide & Rodenticide Act, the Clean Water Act, the Toxic Substances Control Act, and lead paint regulations.

²¹ This list is available at [www.epa.gov/Region3/compliance assistance/hospitals.htm](http://www.epa.gov/Region3/compliance%20assistance/hospitals.htm).

²² Riesel, *supra* note 19, at 8-7 (citing EPA, *Environmental Auditing Policy Statement*, 51 Fed. Reg. 25004 (July 9, 1986)).

²³ Ridgway M. Hall, Jr., "The Evolution and New Directions in Environmental Auditing & Compliance Management," *Natural Resources & Environment* (ABA Section of Environment, Energy, and Resources) (Fall 2009).

²⁴ Riesel at 8-8, 8-9.

²⁵ See New Source Performance Standards, 40 C.F.R. 60.

²⁶ See 40 C.F.R. 355.

²⁷ See 40 C.F.R. 68.

²⁸ See 40 C.F.R. 112 (Clean Water Act's rule on Spill Prevention, Control and Countermeasure Plans).

²⁹ See "Lead Renovation, Repair & Painting Resources," and "PCBs in Caulk in Older Hospitals," postings at the EPA's Healthcare Environmental Resource Center available at www.hercenter.org.

³⁰ Environmental statutes and regulations usually hold "owners" and "operators" liable for non-compliance.

³¹ 65 Fed. Reg. 19618 at 19620.

³² Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005).

³³ 65 Fed. Reg. 19618, 19620.

³⁴ 65 Fed. Reg. 19618, 19621.

³⁵ *Id.* at 19621, 19625.

³⁶ *Id.* at 19621, 19626.

- ³⁷ See *Id.* at 19622 ("EPA will ordinarily extend the 21 day period to allow reasonable time for completion and review of multi-facility audits where: (a) EPA and the entity agree on the timing and scope of the audits prior to their commencement; and (b) the facilities to be audited are identified in advance.").
- ³⁸ *Id.* at 19622.
- ³⁹ *Id.*
- ⁴⁰ *Id.* at 19626 ("If more than 60 days will be needed to correct the violation, the regulated entity must so notify EPA in writing before the 60-day period has passed.").
- ⁴¹ *Id.* at 19622, 19626.
- ⁴² *Id.* at 19622–23, 19626.
- ⁴³ *Id.* at 19623, 19626.
- ⁴⁴ *Id.* at 19626.
- ⁴⁵ 60 Fed. Reg. at 66711.
- ⁴⁶ 65 Fed. Reg. 19618 at 19620 ("EPA has not and will not routinely request copies of audit reports to trigger enforcement investigations.").
- ⁴⁷ Region 4 of EPA has developed a Voluntary Self-Disclosure Template.
- ⁴⁸ Riesel, *supra* note 19, at 8–27.
- ⁴⁹ 65 Fed. Reg. 19618 at 19620.
- ⁵⁰ Riesel, *supra* note 19, at 8-15, 8-16.
- ⁵¹ According to the Audit Policy, "In criminal cases, entities will be expected to provide, at a minimum, the following: access to all requested documents; access to all employees of the disclosing entity; assistance in investigating the violation, any noncompliance problems related to the disclosure, and any environmental consequences related to the violations; access to all information relevant to the violations disclosed, including that portion of the environmental audit report or documentation from the compliance management system that revealed the violation; and access to the individuals who conducted the audit or review." 65 Fed. Reg. 19618 at 19623.
- ⁵² Frank B. Cross, 1 Fed. Envir. Reg. of Real Estate § 2:61 (Oct. 2009) (citing *Reichhold Chemicals, Inc. v. Tetrax, Inc.*, 157 F.R.D. 522 (N.D. Fla. 1994)).
- ⁵³ See Riesel, *supra* note 19, at 8–22 (stating that the Clean Water Act's citizen suit provision has been interpreted to not allow a private individual to pursue a citizen's suit for a "wholly past violation.") (citing *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Foundation, Inc.*, 484 U.S. 49, 57 (1987)).
- ⁵⁴ Frank B. Cross, 1 Fed. Envir. Reg. of Real Estate § 2.61 (Oct. 2009).
- ⁵⁵ Bertram C. Frey and Kathryn McCollough, "Cooperation with Government Agencies under Environmental Audit Privilege/Immunity Laws, Rules, and Policies, available at http://www.epa.gov/region5/enforcement/audit/article_cooperation/upd_coop_intro.html.
- ⁵⁶ Riesel, *supra* note 19, at 8–19.
- ⁵⁷ See John A. Lee and Bertram C. Frey, *Environmental Audit Immunity Laws & Self-Disclosure Policies: A State-By-State Comparison (2004 Update)*, available at http://www.epa.gov/region5/enforcement/audit/article_auditlaws/intro.html, n. 12.
- ⁵⁸ *Id.* at n. 21.

- ⁵⁹ *Id.* at n. 24.
- ⁶⁰ Riesel, *supra* note 19, at 8–12, 8–13.
- ⁶¹ See Letter from Richard Caspe, Division of Enforcement and Compliance Assistance, EPA Region 2 (Dec. 27, 2002) (announcing Region 2's plan to inspect hospitals in New York, New Jersey, Puerto Rico and the U.S. Virgin Islands).
- ⁶² See EPA Press Release, "VA Hospitals in Leavenworth and Topeka, Kansas Agree to Pay Civil Penalty & Implement Plan to Manage Hazardous Wastes," (Aug. 18, 2009); EPA Press Release, "Shawnee Mission Medical Center Agrees to Pay \$83,488 to Settle Allegations of Federal Hazardous Waste Violations," (May 13, 2009); EPA Press Release, "EPA Settles with Gateway Regional Medical Center on Chemical Inventory Reporting Violations," (Jan. 20, 2009).
- ⁶³ Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005) (referring to the Region II Model Facility Audit Agreement).
- ⁶⁴ *Id.*
- ⁶⁵ The EPA Audit Policy states that EPA follows its Investigative Decision Memo (Jan. 12, 1994) and will not employ its criminal enforcement resources on companies which "voluntarily discover, promptly disclose and expeditiously correct violation *unless there is potentially culpable behavior that merits criminal investigation.*" 65 Fed Reg. 19618 at 19620. (emphasis added)
- ⁶⁶ *Id.* at 19620, 19625.
- ⁶⁷ *Id.* at 19620.
- ⁶⁸ It should be remembered that the Audit Policy only provides assurance as to EPA's position on criminal referral. The United States Department of Justice will follow its own policies on voluntary disclosures. *Id.* at 19620.
- ⁶⁹ *Id.* at 19620 ("When a disclosure that meets the terms and conditions of this Policy results in a criminal investigation, EPA will generally not recommend criminal prosecution for the disclosing entity, although the Agency may recommend prosecution for culpable individuals and other entities.").
- ⁷⁰ Riesel, *supra* note 19, at 8-5.
- ⁷¹ "Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance or Disclosure Efforts by the Violator" is published by the United States Department of Justice, Environmental & Natural Resources Division available at www.justice.gov/enrd/Factors-in-decisions.html.
- ⁷² Riesel, *supra* note 19, at 8-4.
- ⁷³ Marc Machlin & Kurt Kissling, *EPA Targets Health Care Institutions: A Prescription for Pollution Prevention*, 34 DEN B-1 (Feb. 22, 2005).
- ⁷⁴ 65 Fed Reg. 19618 at 19624.

⁷⁵ See *"Hospital's Environmental Audits Provide Self-Protection from Aggressive EPA and DEP Enforcement Sanctions,"* Murtha Cullina, LLP (2003) available at www.murthalaw.com.