Title: Minnesota Environmental Results Program for the Non-Hospital Healthcare Sector

Applicant: Minnesota Pollution Control Agency (MPCA)

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Total Project Cost:	Total Budget: $272,425	
	Requested from EPA: $205,000	
	Leveraged, Non-Federally Funded Staff Time: $67,425	
Project Period:	**October 1, 2009 through December 31, 2011**	

Project Abstract:

Since 2002, MPCA has worked on a Health Care Initiative. It began due to wide spread noncompliance with environmental regulations in health care facilities, including violations of hazardous waste, air quality and tank rules. Efforts have thus far focused on the 152 hospitals located within the state. Some metropolitan county hazardous waste programs have begun inspecting and licensing non-hospital healthcare generators and have documented the same wide scale noncompliance as was seen at hospitals. MPCA staff estimate there are as many as 3,000 veterinarians, pharmacies, clinics, and nursing care facilities state-wide and that virtually all of them are out of compliance. Due to the small amount of waste each site generates, many of them would not normally be inspected by MPCA absent a complaint. As an aggregate, the improper disposal of their wastes directly impacts the environment. Preliminary estimates indicate they may improperly dispose of 150,000 pounds of hazardous waste per year. The MPCA will implement an Environmental Results Program (ERP) for this sector that will include outreach, compliance and pollution prevention (P2) assistance, on-line self assessment with accompanying workbook, and a statistically-based assessment of pre-implementation and post-implementation performances by these facilities. As a result of its hospital effort MPCA saw: an initial increase in waste reported; waste streams switched to a desired management method; and then a decrease in waste reported. The first reporting year after the start of the initiative inspections, 2005, saw outstate hospitals report almost 14,000,000 pounds; up from less than 1,000,000 pounds for each of the previous 4 years. The greatest change was a 92% decrease in discharging to a sewer without treatment. Total hospital waste in 2007 was 5.1 million pounds, a 68% decrease from 2006. MPCA expects similar results with the non-hospital healthcare sector.

Statutory Authority and Flexibility: The MPCA is the principal environmental regulatory agency for the state of Minnesota. MPCA has the authority to regulate hazardous waste under Minn. Stat. §116.07 and Minn. R. ch 7045. MPCA's hazardous waste program is an EPA authorized program under 40 CFR part 272, subpart Y. The MPCA has the authority to apply for and accept grants from the U.S. EPA under Minn. Stat. §115A.06, subd. 6 for any of the purposes of the agency and to conduct research and collect and analyze data under Minn. Stat. §115.A.06, subd.10. No regulatory flexibility other than enforcement discretion is needed to implement this project.

State Agency Support: Deputy Commissioner Paul Eger is aware of this application and endorses this project. If this proposal is selected in spring 2009, a letter of endorsement from the Commissioner will be provided with the final work plan.

Pre-proposal Budget Summary:

	Total Project Costs		State Leverage Funds	EPA Funding
State: Minnesota				
Agency: Minnesota Pollution Control Agency				
Project Title: Minnesota Environmental Results Program for the Non-Hospital Healthcare Sector				
		[EPA Redacted as Confidential Budgetary Information]		
Personnel				
Salary	$135,233		$41,282	$93,951
Fringe	$37,865	*salary x 28%*	$11,559	$26,306
Indirect	$47,775	*(salary + fringe) x 27.6%*	$14,584	$33,191
Travel	$6,552	*(invitational)*		$6,552
Capitol Equipment	-		-	-
Supplies	$5,000			$5,000
Contractor	$40,000			$40,000
Other	-		-	-
Total	**$272,425**		**$67,425**	**$205,000**

Leverage funding has been calculated considering only appropriate non-federal funding for activities conducted during the grant period as directed in the solicitation.

Instate travel will be covered by state funding but will not be included as part of MPCA leveraged funding.

Invitational travel for an information exchange meeting is included in the budget as directed in the solicitation.

Pre-proposal Project Narrative:

Problem Statement

The majority of small non-hospital health care facilities are not adequately evaluating their wastes; other noncompliance follows as a result of the failure to evaluate waste. Many discharge pharmaceutical wastes to the sewer without treatment, including those that are hazardous. We are beginning to see disparity between metropolitan and out-state compliance as metropolitan counties start inspecting and licensing these generators. The large number of these facilities compared to our small number of compliance and enforcement staff has thus far prevented us from taking the traditional regulatory approach which we used successfully with the closely aligned sector of hospitals.

Background

MPCA hazardous waste rules, Minn. R.ch. 7045 applies to all generators of hazardous waste in Minnesota. MPCA has authority to implement the self-assessment tool necessary for this ERP under its authority to require hazardous waste generators to submit information to the MPCA and under its authority to provide technical assistance to hazardous waste generators. Minn. Stat. §§ 116.07, subd. 9 and 116.091, subd. 1 require regulated parties to provide information to the MPCA relevant to pollution or compliance with rules and statutes of the MPCA or to provide any other information that the agency may reasonably require. The MPCA also has the authority under Minn. Stat. § 115A.152 to provide technical assistance to hazardous waste generators to improve management of hazardous waste and comply with hazardous waste requirements.

The Hazardous Waste regulatory program of the MPCA proposes to conduct an ERP with the non-hospital healthcare sector. This ERP will blend self-assessment, education/assistance, and small random sample inspections to elicit improvement and draw statistically valid conclusions about compliance, cost-effectively. MPCA has committed existing staff to this project and will hire additional Hazardous Waste staff to conduct the work of this ERP. This new hire will be at the level of Pollution Control Specialist, unclassified, temporary for 2.25 years.

Major roles are as follows: Grant Hire, ERP duties; Phyllis Strong, P2 Coordinator, grant manager; Tanya Maurice, Hazardous Waste Compliance Coordinator, lead investigator; Brandon Finke, RCRA Pollution Control Specialist Senior, mentor to grant position; and Al Innes, P2 staff, technical support for ERP.

A contractor will be hired to assist MPCA Information Systems Office (ISO) staff in the development and on-going support of the on-line assessment. MPCA communications and graphics staff will also contribute to this ERP work. The Minnesota Technical Assistance Program (MnTAP) will serve as a P2 resource for this project.

The on-line self assessment will be mandatory. We expect most facilities will be in noncompliance. Encouragement of P2 practices will be integrated throughout all parts of this ERP and will provide a means for the regulated party to move beyond compliance.

Program Guidelines and Eligibility requirements

Adopting an ERP approach allows for innovation in environmental permitting. Refining the ERP tool and incorporating an on-line approach to self assessment could provide more innovation. Funding requested is within the available range.

Anticipated start date is October 1, 2009. Grant ends in 2.25 years, within the four year limit.

Threshold Criteria

#1) Project activities are authorized under the Clean Water Act and the Solid Waste Disposal Act. Project incorporates gathering information which can be transferred to others so that learning will occur from this innovative approach.

#2) EPA Strategic Plan - This project directly addresses hazardous waste pollution, a single media. The outcomes of this project impact the protection of water pollution, another media.

Goal 5: Compliance and Environmental Stewardship

The MPCA will use its enforcement discretion to not take enforcement action against non-hospital health care generators covered by this ERP who participate in the self assessment process and who return to compliance within the MPCA's stated period to return to compliance. This is as an incentive. Inspections will monitor compliance and follow-up to those inspections will serve to correct and deter future non-compliance.

Objective 5.2 Improve Environmental Performance through P2 and Other Stewardship Practices

By using knowledge gained through our hospital outreach, working with stakeholders, incorporating P2 assistance throughout all parts of this ERP, and using MnTAP as a resource we will promote solid P2 practices to this industry sector. Our hospital inspections and outreach saw waste reductions and improvements in hazardous waste management. We expect similar results through this ERP.

Sub-objective 5.2.3 Promote Environmental Policy Innovation

After applying this alternative approach we will analyze, summarize, and report findings. We expect these findings, particularly as they relate to pharmaceuticals, to be useful to MPCA as it develops policy to address its management of emerging issues. This is a MPCA priority; see http://www.pca.state.mn.us/publications/reports/lrp-ear-2sy08.pdf. We expect these findings to also be useful to EPA as it addresses the risks associated with emerging contaminants.

Goal 2: Clean and Safe Water

Pharmaceutical waste is generated at health care facilities and commonly discharged to POTWs. Traditional wastewater treatment at POTWs is not specifically designed to remove pharmaceuticals and their presence has been documented in surface waters across the United States. Pharmaceutical wastes include mercury preservatives, warfarin, chemotherapy agents, controlled substances, and endocrine disrupting compounds. Uncontrolled exposures to these compounds are associated with negative impacts to human health. We expect this ERP to reduce this exposure.

#3) We intend to meet all requirements of the solicitation.

Project Objectives

This ERP will reach across the non-hospital health care sector and bring the majority of facilities into compliance with hazardous waste rules and will provide education in P2 practices.

This project will result in proper waste evaluation, correct identification and management of hazardous wastes, implementation of P2 practices, reductions in waste generated, and fewer pharmaceuticals entering our surface waters.

Methodology or Technical Approach

Our focus will be on hazardous waste compliance with our main emphasis on evaluation and management of pharmaceuticals.

Statistical Framework:

Current estimate of non-hospital health care facilities to be included in the project: 3,059

Confidence level sought: 90%

Target for minimum number of inspections in Year 1: 35

1-sample margin of error: 13.3%

This means that if inspection data shows 50% of facilities are in compliance on a particular issue, we can state that we are 90% confident that the true proportion of facilities in compliance on that issue is between 36.7% and 63.3%. 1-sample margins of error would apply for the data collected in any given year.

Target for minimum number of inspections in Year 2: 35

2-sample margin of error: 19.8%

This means that if inspection data shows a 40% improvement in compliance from Year 1 to Year 2 (±19.8%), we can state that we are 90% confident that the actual rate of improvement is between 21.2% and 59.8%. This also means that any difference between Year 1 and Year 2 data at this level of inspections must exceed 19.8% in order for us to be able to make such a statement, or to call the difference "statistically significant."

MPCA believes that these statistical limitations to its project design are an acceptable trade-off with the number of inspections we are sure to be able to deliver. Our experience with hospitals shows that the vast majority return to compliance on most issues within 6 to 12 months so that baseline-to-follow-up changes will exceed the projected margins of error.

Measures

The following metrics come from MPCA's Hospital multimedia initiative (Outstate Hospitals in FFY 2008 unless otherwise noted) and are presented to illustrate possibilities, not present numeric goals for the proposed non-hospital health care project.

Outputs

Completed inspections: 34

Documents: Notice of Violation (NOV) - 37; Letter of Warning - 3; in-process - 2 (1 group NOV for 11 hospitals); and Request for Information - 2.

Enforced RCRA violations: disposal - 29; storage - 16

Outcomes

Changes in Behavior

Hazardous waste reporting – In CY 2007, the compliance rate for hazardous waste reporting was 62%, a 7% increase over CY 2006.

Sewer notifications – Thirty new forms were submitted, plus one from an uninspected surgery center.

Shifts to desired management methods – There was 92% decrease in discharging to a sewer without treatment.

Changes in Conditions

Amount of waste properly managed – Reporting shows 33,000,000 pounds, which is the 3-year cumulative minus baseline (2005-2007).

Waste Reduction – There was a 68% decrease in total hazardous waste reported.

Waste Reduction – There was a 14% decrease in total pharmaceutical waste reported.

We expect to see similar results from our non-hospital health care sector ERP. We will confer with regulatory programs that have completed ERPs and use this information to help us make estimates of compliance and performance results for this project for the full proposal. Our ERP project will have an additional output of number completing a self-assessment.

Throughout FFY 09	1. Develop inspection and enforcement protocol.
Oct-Dec 2008	2. Identify universe of facilities.
	3. Develop project and grant pre-proposal.
Jan-Mar 2009	4. Develop ERP program narrative for sector.
	5. Develop business process for on-line self assessment.
	6. Develop business specifications for on-line self assessment.
Apr-Jun 2009	7. Flesh out SIG work plan and QAPP (practices for gathering primary and secondary data).
	8. In partnership with associations, develop outreach materials to publicize the project.
	9. Develop system functional specifications for on-line self assessment.
	10. Develop self assessment.
	11. Develop computer assistance contract Request for Proposal (RFP).
July-Sep 2009	12. Finalize and post on web and mail outreach materials.
	13. Continue follow up work for computer assistance contract RFP.
	14. Develop inspection training for grant position.
	15. Finalize business and system functional specifications for on-line self assessment.
Grant Begins	Hire grant position.
Throughout grant (**FFY 10**, **FFY 11**, **And 1st quarter** of **FFY 12**)	16. Ensure grant position complies with administrative policies and procedures.
	17. Ensure grant position completes employee development and training.
	18. Complete compliance and enforcement follow up to inspections.
	19. Conduct outreach to industry partners.
	20. Respond to requests for assistance.
	21. Complete data tracking.
	22. Conduct monthly regulatory staff check-ins with Hazardous Waste team.
	23. Conduct monthly check-ins for regulatory staff with grant manager.
	24. Complete and submit quarterly grant reports.
	25. Complete work to transfer findings to regulatory/ERP/P2 partners. (Meeting near end of ERP.)
Throughout FFY 10	26. Complete/provide Hazardous Waste Program Training and mentoring for grant position.

Oct-Dec 2009	27. Complete computer assistance contract RFP follow up tasks.
	28. Conduct inspection training for grant position.
	29. Begin baseline inspections (50% inspections - 17 in timeframe).
	30. Hire computer assistance contractor.
	31. Begin development of on-line self assessment.
	32. Participate in testing of on-line self assessment.
Jan-Mar 2010	33. Finish baseline inspections (18 in timeframe).
	34. Develop education materials.
	35. Participate in testing of on-line self assessment.
	36. Finish development of on-line self assessment.
	37. Develop workbook to match on-line self assessment.
	38. Develop industry workshops (for 4 areas of focus, with 10 events).
Apr-Jun 2010	39. Post self-certification and workbook on-line.
	40. Notify affected parties of posted materials, and direct on-line for instructions.
	41. Complete data management and analysis for baseline.
	42. Conduct workshops (5 events in timeframe).
Jul-Sep 2010	43. Finish workshops (5 events in timeframe).
Oct-Dec 2010	44. Develop post-cert inspection and data management protocol (draft and review).
Jan-Mar 2011	45. Finish post-certification and data routines.
	46. Begin processing certification data (review, data management).
Apr-Jun 2011	47. Finalize certification data processing.
	48. Begin post-certification inspections (17 in timeframe).
Jul-Sep 2011	49. Finish post-certification inspections (18 in timeframe).
Oct - Dec 2011	50. Finalize post-certification data analysis.
	51. Final Grant Report
Grant Ends	

Collaborations or Partnerships

Within the MPCA, collaboration among Hazardous Waste Compliance and Enforcement, P2, ISO, Financial Assistance and Budgeting, and Communication and Outreach management and staff has already occurred during the development of this pre-proposal. These efforts will continue if this project goes forward.

MPCA partnerships will serve this proposed project well; new partnerships will develop and existing ones will be strengthened as a result of this work. Partners may include, but are not limited to: staff and management from the metropolitan hazardous waste programs of the Solid Waste Management Coordinating Board; Metropolitan Council of Environmental Services; MnTAP; Minnesota Department of Health; licensing boards such as Minnesota's Board of Pharmacy; regulatory and assistance staff from other states that have experience conducting ERPs; EPA; professional and trade associations such as the MN Veterinary Association, and MN Health and Housing Alliance; and health care related working groups, such as Healthcare Environmental Awareness and Resource Recovery Team.

Public Involvement Process

MPCA is committed to meeting public involvement needs. We will examine our situation further if invited to make a full proposal and will make any necessary changes to our preliminary assessment. If appropriate, we will do further work to follow and implement EPA's seven basic steps for effective public involvement as described in *Public Involvement Policy of the U.S. EPA, May 2003*.

Preliminary assessment:

Our proposed project focuses on educating the non-hospital health care sector to ensure the proper management of hazardous waste, especially pharmaceuticals. The relationship of this work to the general public should be noncontroversial and positive. Currently we see that veterinary hospitals and offices, pharmacies, clinics, and nursing (long-term care/hospice/etc.) facilities do not adequately evaluate their waste. The waste is frequently discharged to the sewer without treatment. This management method is not always appropriate. It can lead to contamination of surface waters which has a negative impact on human health. If this project ultimately is protective of water quality and hence human health, it is expected that the general public should be supportive.

We will work closely with the professional and trade associations, licensing boards, and work groups of our sector through out this proposed project. We will gather sector input from these industry stakeholders, develop outreach materials to publicize the project; develop content for educational materials, and training outlets; and conduct industry training events.

Considering the scope of our work and our limited resources we feel we can serve the general public needs by having any materials developed during this project, that are deemed appropriate to these purposes, available via the MPCA web page. These postings could not only serve the industry sector needs but improve public understanding as well.

These links are examples of possible electronic routes we could use to provide information to the public: Background on Environmental Issues,
http://www.pca.state.mn.us/newscenter/background.html
Hot Topics, http://www.pca.state.mn.us/hot/index.html
Healthcare Industry, http://www.pca.state.mn.us/industry/healthcare.html
Quarterly Summary of Enforcement Actions,
http://www.pca.state.mn.us/newscenter/enforcement.html

Transferring Innovation

An on-line self assessment is a tool that could readily be adopted for other purposes. EPA's Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals and its proposed Information Collection Request: Study of Unused Pharmaceuticals from Medical and Veterinary Facilities documents this sector as an EPA priority. If we are able to develop innovative practices, they seem well placed for transfer. A next step could transfer this approach to medical laboratories.

We are committed to:
- Documenting and publicizing our findings to our stakeholders, and making this information available to other jurisdictions.
- Providing this information in a form both easily accessible and understandable.
- Hosting one or more information exchange meetings to facilitate the transfer of information or innovation.
- Sharing our learning within our state and beyond to promote developing innovative environmental problem-solving as "a way of doing business" within our state and beyond.
- Providing consultation and mentoring to other states or tribes wishing to adopt similar innovations.
- Participating in national or regional workshops and symposia to report on project progress.
- Advancing the state of knowledge of tools for strategic innovation;
- Addressing the need for and new applications of the ERP approach as a model for "next generation" environmental protection.

Methods to help carry out these commitments could include:
- Work with our ISO, graphics, and communication staff to ensure information is accessible and understandable.
- Use technology to communicate and conduct meetings and convene face-to-face.
- Participate and share information through regulatory work groups, the States ERP Consortium, the National Pollution Prevention Roundtable and the Great Lakes Regional Pollution Prevention Roundtable and their workgroups. Make related presentation(s) at National Environmental Partnership Summit.

Project Technical Feasibility

We have preliminary work plans to address the needs to carry out regulatory aspects, integrate P2, conduct outreach and education, and provide for development of the on-line assessment. We have support in place to successfully complete this project. Task and timeline development have been based on the ERP model and its past use, our available resources, and the history of the capabilities of our staff. Technical issues concerning the on-line self assessment have been discussed with our ISO personnel. We plan to smooth out problems and reduce time required by front-end loading work before the grant begins and requiring the contractor to supply product in a standard, and supply adequate documentation for agency staff to continue work as necessary.

Reporting Requirements

MPCA is committed to electronically submitting the mandatory quarterly reports and detailed final project report in a timely fashion and successfully meeting all of EPA's requirements for these reports. MPCA is committed to sharing all data collected with EPA for the purpose of assessment on a regional and/or national level.

Past Performance - Programmatic Capability and Reporting Environmental Results:

MPCA has experience in managing federal grants and has managed an ERP project.

MPCA is a signatory to the Memorandum of Agreement to the National P2 Results Data Management System. MPCA reported data to this system for 2006, 2007, and for 2008 up to June 30. MPCA is committed to reporting data to this system yearly.

1. Dairy ERP Grant

MPCA is currently completing final analysis and reporting on a dairy ERP partially funded by a 2004 SIG cooperative agreement. This complex project changed directions and was altered and extended at no cost following discussion with EPA and its ERP contractor. The project awaits completion of some tasks including analysis of several objectives and submittal of the final project report, but all agreed-upon tasks and intended objectives scheduled to date have been achieved.

Reports were completed for each quarter except the final one ending September 30, 2008, which will be covered in the final report due December 31. Some quarterly reports were delayed from their due date if follow-up analysis of work in that quarter was still under way. Any delays were communicated to and approved by EPA project officers.

Dairy ERP project staff members have concluded that delays were usually due to under-capacity of the partner program, which placed more project responsibility back on the Prevention and Assistance Division staff coordinating and co-managing the project. Based on these lessons learned, Prevention and Assistance has invested extra time in the pre-proposal phase of this proposed project to reach a clear understanding with the partner program on the respective roles and resources being committed.

2. Recently completed P2 Grant

MPCA has managed and completed EPA P2 grants since they have been available. The most recent completed P2 grant was in place from July 1, 2006 through June 30, 2008. Semi-annual Progress Reports were required. All reports were submitted. If reports were delayed, the P2 grant manager communicated with the EPA project officer to gain approval. In August, 2007, MPCA made a transition to the current P2 grant manager.

The first report due after the transition was the Semi-Annual report due in January, 2008. It was submitted on time. The grant ended on June 30, 2008. The Final Progress Report and all fiscal forms were submitted on time. This grant was financially closed on August 11, 2008.

No duties suffered from the transition. The total project completed was 100%; all agreed-upon tasks under this agreement were completed and all intended objectives were achieved. The total budget completed was 100%. MPCA was able to fully utilize the $165,700 in P2 funds for this 2 year project.

3. Current P2 Grant

MPCA is currently managing an EPA P2 grant which began October 1, 2008 and will end September 30, 2009. Work has begun to manage the projects of this grant. MPCA is committed to successfully meeting the expectations of this grant and reporting results to EPA within all applicable deadlines.