Comments on Minnesota Pollution Control Agency Draft Certification Policy

Comment	Minnesota Pollution Control Response
1st paragraph	
With the Minnesota Department of Health (MDH) already having a complete certification program, it appears that the Minnesota Pollution Control Agency (MPCA) is going to have a duplicate program or to a lesser extent, a policy that is already covered by MDH Certification Program. What is the intent of the draft policy? Has there been input from MDH Certification Group and what are the ramifications for permits that are currently governed by the MDH?	The intent of the draft policy is to allow laboratories a greater number of options for certification so they can find something that suits their needs and is acceptable to the MPCA. The MPCA does not intend to start certifying laboratories. The MDH certification unit has had the opportunity to review and comment on the MPCA Certification Policy. The only permits MDH governs are for drinking water wells. The MPCA is responsible for National Pollutant Discharge Elimination System (NPDES) permits. The language in those permits will need to be modified to align with our policy.
We believe that there are areas that our clients could be impacted by the Draft Policy. One example is the impact of the Draft Policy to the State Brownfields Grant Program where MPCA program compliance is necessary to successfully achieve Brownfields Grant Application approval and potential site clean-up cost recovery. In general, we believe this Draft Policy will present a challenge for us to successfully meet the unique client and laboratory needs as the requirements are still somewhat ambiguous.	During a verbal discussion to clarify what is being asked, it was mentioned that it was unclear how labs would be affected by language in permits, guidance and Quality Assurance Project Plans that seems to contradict this policy. The MPCA is still working on the specifics of implementation. The Quality Assurance (QA) staff will work with other MPCA Divisions to align their guidance documents with this policy and to implement the change for cost recovery programs.
2nd paragraph	
The Draft Policy, as written, would allow MPCA staff to accept data from laboratories without either direct MDH certification or certification through an MDH reciprocity agreement. This would be unfair to Minnesota labs, unless agreements with other states include reciprocity. For instance, if you agree to accept data from labs certified by Indiana, it would only be fair that Indiana accept the work of Minnesota labs. Any lab in the country already has the ability to work on Minnesota projects and have their data accepted. All they need to do is become certified by MDH. The Draft Policy would give an advantage to a few large labs who would like to do business in Minnesota without paying the same fees Minnesota labs pay. It would suggest moving lab operations from Minnesota to a state where fees were cheaper. The idea of the policy is good if reciprocity is included. Otherwise the result would be unfair competition.	MPCA deals with the primary accrediting authority for any certification of a laboratory, and therefore, there is no advantage to the State in dealing with any reciprocity or secondary accreditation. MPCA does not require any specific state or program only certification from an accepted certification program as will be defined by Appendix 2 of the Certification Policy. Therefore, a laboratory in Minnesota or any other state may choose which program to be certified by eliminating any advantage enjoyed by any particular state on certification fees, either primary or secondary.

Comment	Minnesota Pollution Control Response
Has the MPCA discussed doing limited “Approvals” for laboratories if the laboratory can prove that all required quality systems, QA Manuals, Standard Operating Procedures (SOPs), and acceptable proficiency test samples (PTs) are in place?	Not at this time.
MPCA staff already reviews our laboratory data. Has the agency discussed doing its own audits of laboratories doing work strictly under their programs to be sure that the quality systems are in place? There would have to be a fee for this, but with the limited scope it could be done for a much lower cost than full MDH certification costs.	Not at this time.
If we are already certified for a particular test, by the MDH, does this mean we will be required to get a certification from the MPCA as well? If this is the case, how much is the new certification going to cost?	No, the MPCA does not certify labs. The certification policy is only meant to clarify MPCA requirements for a certification program to be recognized. If a laboratory would like to remain MDH certified, that is an acceptable option. There is no cost to laboratories associated with this policy, only the ability to choose a certification authority.
The new policy states that the MPCA will only recognize the primary accreditation body issuing certification. For an out-of-state lab whose primary National Environmental Laboratory Accreditation Program (NELAP) accreditation is through a state other than Minnesota (e.g. Oregon), will that lab also need to maintain secondary accreditation by the MDH? This policy seems to indicate that out-of-state labs do not need certification through MDH to do work in Minnesota.	Based on our Policy, out of state labs that have primary certification through states or programs listed on Attachment 2, which is in the process of being established, are acceptable to the MPCA and do not need secondary accreditation to do work for MPCA. Attachment 2 will list the Primary ABs that have agreed to work with the MPCA and acknowledge the MPCA QC Policy in auditing labs that perform work in Minnesota.
So a lab having multiple states which are not NELAC would have multiple options?	That is correct.
Must alternate test procedures (ATPs) approved by the U.S. Environmental Protection Agency (EPA) be approved by Region 5 specifically or can another Region grant approval?	We do not know at this time. We will ask for a confirmation from Region 5 but probably not. We believe Region 5 will tell us that an ATP can be granted from another region and recognized by Region 5 and, therefore, the MPCA.
As a laboratory located in the State of Minnesota which desires NELAC accreditation, we are required to have our accrediting body be MDH. While this policy appears to give laboratories a choice in certification body, the reality will be our laboratory will still require MDH certification due to the NELAC requirement. If the goal of the policy is for the MPCA to accept data from other laboratories that are not certified by MDH, it should be noted that these laboratories are not paying certification fees to the State of Minnesota. Our laboratory currently is paying about $20,000 a year to the MDH for our laboratory certification. We believe this would be a tremendous unfair business advantage to Non-MDH Certified laboratories that would be pursuing laboratory work in Minnesota where these laboratories do not pay MDH certification fees.	The MPCA already accepts data from laboratories which have primary certification in other states and by other certification bodies. The MPCA must deal with the primary accreditation body for each laboratory for data quality issues. Our main concern is with the quality of the data upon which decisions are based. Secondary accreditation is of no benefit to the MPCA because secondary accreditation authorities do not directly audit laboratories and cannot assist the MPCA with data quality investigations. The MPCA does not have anything to do with MDH fees. For questions on the MDH fee structure, please contact MDH.
From the discussions during the meeting, our understanding of the intent of this policy is that the MPCA will be contacting TNI Accrediting Bodies (ABs), in addition to states that offer non-TNI accreditation to determine if those states are willing to audit to the criteria in the MPCA Laboratory Quality Control and Data Policy. Subsequently, a list of states will be created that may do work for the MPCA in the state of Minnesota. There will be no requirement for these laboratories to seek primary or secondary accreditation through the MDH certification unit.	This is correct. The MPCA will be publishing a list of certification bodies that are acceptable to the MPCA. The MPCA does not recognize secondary accreditation because the MPCA will always be required to work with the primary accreditation authority on laboratory data issues. The primary accreditation authority is the only accreditation body that can deal directly with a laboratory on accreditation, method interpretation and data reporting issues.

Comment	Minnesota Pollution Control Response
3rd paragraph	
Will labs then have six months to add new analytes and tests added each July 1 to Attachment 3 such that they may add on their next renewal cycle?	Yes, Attachment 3 will be updated by July 1 of each calendar year so that laboratories will have time to review new MPCA requirements and decide if they want to add additional fields of testing to their certification by January 1 of the following year, six months after the possible addition of new MPCA certification requirements.
The MPCA requesting data and performing an onsite audit could mean another audit in addition to the certification audit – who would be charged for this?	The MPCA currently requests data and supporting information when MPCA project managers have questions about information being reported to the Agency. This can be as simple as a phone call to clarify information or as detailed as an onsite audit. There is no direct charge to the lab for this type of follow up on the part of the MPCA. MPCA will contact the primary certification authority for follow up should there be severe enough issues to warrant a follow up audit.
With the proposed timeline of January 1, 2012, to "apply and gain certification", it would seem that laboratories would need to select their accrediting authority and certifying fields of testing without a final policy to follow? This would limit the laboratory's ability to comply and seems unrealistic.	Laboratories do not need to change their accreditation authorities to be in compliance with the Certification Policy, unless their primary accreditation authority is not on the Attachment 2 list of approved accreditation authorities. The list of methods and analytes requiring certification is finalized and is posted on the MPCA Quality System site. Since July of 2010, laboratories have known that they would need to have the Resource Conservation and Recovery Act (RCRA) 2007 versions of methods on their certificates by January 1, 2012, per the MPCA Laboratory Quality Control and Data Policy. Laboratories should contact their MDH Accreditation Officer for details on how to update their Accreditation to make the switch to the 2007 versions of RCRA methods.
MPCA minimum criteria	
Item #2- What if laboratory SOPs conflict with MPCA Program Guidance and Policy due to different state requirements – especially for laboratories located in other states that have state certification or NELAC primacy accreditation from a out state(non-MN) NELAC accrediting body such as OR, FL, CA, NY NELAC.	The MPCA is selecting accreditation bodies that are willing to work with MPCA program and QC requirements. It is very typical for laboratories that perform work in multiple states to add state specific requirements into their SOPs. It should not matter which accreditation body does the primary accreditation for a lab.
Item #3- Can verifying data at the bench level be looking at data and not actually asking questions of the analyst? – thinking of Arizona type audits which tend to be less talking with staff and more data review.	MPCA has had and will continue to have conversations with ABs ensuring they look at data as a component of a bench level audit. MPCA requires the auditor to also verify that the data comply with the laboratory SOP and that specific individuals responsible for producing the data use and understand the SOP and reference method(s) upon which the SOP is based as well as any applicable state specific requirements.
Item #5- Is an ISO auditor supposed to audit a lab against the ISO standards and MPCA Laboratory QC and Data Policy? Likewise, you are expecting labs that have NELAC primacy through any of the other NELAC AB's (other than Minnesota) to also audit the lab(s) against the MPCA Program Guidance and Policy and NELAC?	Yes, with the understanding that ABs will not change their process to accommodate the MPCA, but will consider the QC Policy when working with laboratories that work in Minnesota. Additionally, the laboratories external to Minnesota have received the Policy and will be held to this standard by MPCA. This is not a change in MPCA requirements. Parties submitting data to the MPCA have always been required to follow MPCA program guidance.

Comment	Minnesota Pollution Control Response
Item #6- Some programs like Arizona do not require PTs for both water and soil (semi volatile organic compound (SVOC) water PT is analyzed but SVOC soil is not needed) unless only have a soil method.	We recognize there may be some variability in PT requirements from one accreditation body to the next. PT samples are just one tool used as an indicator of data quality.
Final paragraph	
There are currently 20 out of state laboratories carrying certification in Minnesota. The loss of revenue related to their accreditation fees would be approximately $295,000 for the state of Minnesota. This does not include the revenue lost based on new labs that would now be allowed to perform work in Minnesota, thus taking away work from all of the laboratories that are currently certified and reside in Minnesota. Small labs in Minnesota will be in jeopardy of downsizing or closing due to price pressure that will exist from all the national firms. The [sic] will result in loss of Minnesotans jobs, and this would extend beyond the laboratory industry to consultants and other support services.	The MPCA does not deal with laboratory accreditation fees. MPCA recommends laboratories direct questions about certification fees to MDH. Because labs will have a choice of accreditation bodies under the Certification Policy, they should be able to find a program that will meet their certification needs and will be able to compare costs, saving money and, thereby, helping them to be more competitive.
It is unclear the benefits of this proposed policy as it does not guarantee that the quality of the data submitted to the MPCA will be any better than it is today. While the short term cost saving measure of reducing state expenditures through the loss of jobs in the state of Minnesota Department of Health certification unit will be noted. We are concerned that the lack of oversight may impact data quality, consistent review of laboratories providing data to the MPCA, and subsequently impacts to the environment of our state.	We disagree. The MPCA will be dealing directly with the primary accreditation bodies who audit the laboratories on data quality issues so, there should be improved oversight of certified labs and, therefore, an improvement in the ability of the MPCA to make informed decisions based on the data it receives. Secondary accreditation offers no guarantee of quality of data as it consists of paying a fee and submitting documents. The data user is responsible for speaking directly to ABs to ensure quality.
As a data user, we strive to achieve the appropriate level of data quality while balancing the need for data affordability and market/choice. More rigorous agency requirements over the last decade have increased data quality in the environmental laboratory, but that has come with increased cost and complexity for the laboratory community. In order to keep operating costs in check and stay competitive, laboratories have often reduced the analyses for which they maintain certification. In turn, this has resulted in a decreased choice of laboratories available for performing analyses in the marketplace. The existing Minnesota Department of Health accreditation is already more expensive to obtain/maintain than many states, and we are concerned that this additional MPCA program (as described in the Draft Policy) will increase cost and complexity to the laboratories. This could add to the reduction of laboratory capacity in Minnesota that is already occurring. For example, the policy states that MPCA could audit a lab in addition to audits by the primary accrediting authority. This will add cost/complexity to the laboratories by adding additional action items/document changes/responses etc., for the laboratory to follow up on. In addition, who pays for the MPCA auditor is not clear at this time. While auditing is an important tool to assess laboratory performance, multiple auditors and programs will eventually conflict with each other, adding confusion and cost.	The MPCA Laboratory Certification Policy should not add costs to laboratories. By providing labs with certification choices, they should be able to find a program that meets both their certification needs and be able to compare costs of various programs. The MPCA has no input into laboratory accreditation fees. Because labs will have a choice of accreditation bodies under the Certification Policy, they should be able to find a program that will meet their certification needs and will be able to compare costs, potentially saving money and, thereby, helping them to be more competitive. The MPCA currently requests data and supporting information when MPCA project managers have questions about information being reported to the Agency. This is not a change in MPCA business practice. This can be as simple as a phone call to clarify information or as detailed as an onsite audit. There is no direct charge to the lab for this type of follow up on the part of the MPCA.

Comment	Minnesota Pollution Control Response
Attachment 1	
Can you make other NELAC states do this?	We were asked by MDH to document MPCA QC requirements because the TNI Standard specifically states that labs must meet the requirements of regulatory authorities. We are contacting the NELAC Accreditation Bodies (ABs) to determine which ones will be willing to consider MPCA requirements in auditing labs that do work in the State of Minnesota. We will include the list of ABs that are willing to work with the MPCA in Attachment 2. MPCA cannot make NELAC states do anything, we simply will choose not to accept data from a state that does not acknowledge the MPCA QC Policy and meet minimum certification requirements of the Agency.
I am reviewing the Attachment 1 (MPCA Laboratory QC and Data Policy) of the Draft Certification Policy that may go into effect January 1, 2012, and I see that the MPCA must directly receive results and corrective actions for PT samples. I am wondering where laboratories will submit this data to (e-mail, fax, etc.). It is my understanding that right now, laboratories are not required to submit PT data directly to the MPCA.	The MPCA is currently reserving the right to ask for this information as needed for data review purposes. PT results can be sent to qa.questions.mpca@state.mn.us.
Attachment 2	
I have a question regarding the draft certification policies presented at the QA meeting held August 17, 2011. Is Attachment 2 of the Certification Policy available for review? I would like to know what states and accreditation authorities the MPCA recognizes. If this is not yet available, could you provide a timeframe in which this list will be published?	Attachment 2 is not yet available for review. The MPCA is in the process of contacting various state and national programs with our program requirements. We hope to compile the list of recognized certification/accreditation authorities and post it on the MPCA Quality System webpage by January 1st, 2012. We will send out an announcement when the list is available.
Laboratory certification fees through the MDH are extremely high, especially for municipal and small not-for-profit laboratories. Are there other private organizations, or states with reciprocity the MPCA recognizes for certification?	Attachment 2 will list the ABs and programs the MPCA currently recognizes. The MPCA will be recognizing only the primary accreditation body, not any reciprocal agreements.
It is inferred that Attachment 2 of the Draft Policy (not yet received) will list the state or accreditation authorities and that these authorities have agreed to audit the laboratories to the MPCA Draft Policy. Will quality-based system accreditation authorities (i.e., NELAC, ISO, A2LA, etc.) be willing to audit data and verify the findings at the bench level? The Draft Policy seems to lack specific details regarding auditing cycles, (e.g., what would happen if the accrediting authority does not meet the three year cycle for auditing?). While a certification authority can claim to audit each laboratory a minimum of once every three years, in practice, there are cases where this frequency may not occur. This is a complex issue involving the laboratories, certification authorities, and data users. How will the MPCA resolve this issue?	Yes, the MPCA will only recognize ABs that are willing to audit data to the bench level, not just perform a systems audit. It is important that an auditor determine that a lab is actually producing good quality data, not just theoretically capable of producing good quality data. The TNI requirement is for labs to undergo an onsite audit by their primary accreditation body every two years so they should be fully compliant with the MPCA three year requirement. It would not be reasonable for the MPCA to penalize a laboratory if their AB is behind in their audit cycle, however, an AB found to be significantly and repeatedly in violation of their own standard may be dropped from Attachment 2 as an MPCA recognized AB.

Comment	Minnesota Pollution Control Response
Attachment 3	
In 2007, the MDH announced that it would no longer be certifying laboratories for any Standard Methods that were not the Online revision. We purchased an Online Standard Methods subscription and updated all of our SOPs to reflect the Online edition. When you asked us to review the Attachment 3, I looked into 40 CFR 136.3, where unfortunately, the Online version of Standard Methods are not listed as acceptable. How do you want laboratories to handle that discrepancy? Will the MPCA accept the Online revision of Standard Methods as a reference method for Clean Water Program (CWP) analyses even though it is not listed on 40 CFR 136.3, or will we have to revert to an older revision of Standard Methods and will the MDH be okay with that for our certification? (I do not see the Online edition specified on the Fields of Accreditation (FOAs) offered by MDH like it used to be, maybe MDH loosened their policy and I was unaware of the change.)	Here is the link for the electronic version of 40 CFR 136. Part 136.3 does list Online versions of Standard Methods as approved for use under the Clean Water Act. You will need to contact the MDH Certification Program about the Fields of Accreditation question.
Just a question on notification process - will a message be sent to labs when Attachment 3 listing is posted to the web or do labs need to keep checking? If the latter, when do you expect the list to be posted?	The MPCA QA unit is working on becoming part of the GovDelivery notification system so that notices can be sent out easily when there are changes to our webpage. Attachment 3 is now posted on the MPCA Quality System web page under “Laboratory Guidance and References”.
In Attachment 3, MPCA notes that they require certification for analytes that are not offered for certification through MDH. How should this be handled? Attachment 3 does not list matrices.	The MPCA will continue to try to work with the ABs to make MPCA required analytes and methods available for certification. Labs wishing to be certified for specific tests or analytes within a method should obtain certification that is as close as possible to Attachment 3. If certification is not available for a specific analyte within a method, it should be noted on the lab’s analytical report that certification is not available for a specific compound(s). The Clean Water Program methods only apply to water. Certification should be obtain for the major matrices for RCRA methods, like soil, water, and, when applicable, air, if a lab wishes to use the RCRA methods for reporting results from these matrices.
Attachment 3 of the Draft Policy attempts to clarify the analytes that require certification. MPCA recognizes that some analytes are not currently available for certification through the MDH. How will MPCA address these and any other discrepancies between the various accrediting authority analyte lists? Will certification by multiple accrediting bodies be necessary to meet this Draft Policy?	See above response. Certification will not be required from multiple ABs unless a primary AB does not offer an entire method that is required to be certified.
How will this Draft Policy be incorporated into the MPCA Guidance documents now on the website? How will this Draft Policy apply/differ for captive laboratories (i.e., NPDES testing facilities) as compared to commercial laboratories?	The MPCA QA Unit is still looking at how to resolve any contradictions between MPCA Guidance and the Certification Policy until the Guidance documents can be updated. All of the elements of the Certification Policy apply to wastewater and captive labs except Attachment 1, the MPCA Quality Control and Data Policy. A QC policy specific to small labs will be published in the future.