Great Lakes Fish Monitoring and Surveillance Program

Quality Management Plan

Version 2.0, November 2012

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Acronyms and Abbreviations

BEC	Binational Executive Committee
BTS	Binational Toxics Strategy
CEC	Contaminants of Emerging Concern
CIO	Chief Information Officer
CSMI	Cooperative Science and Monitoring Initiative
CSP	Contaminants Surveillance Program
CSC	Computer Sciences Corporation
DNR	Department of Natural Resources
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EPAAR	EPA Acquisition Regulations
FAR	Federal Acquisition Regulations
FDA	U.S. Food and Drug Administration
GLENDA	Great Lakes Environmental Database
GLFC	Great Lakes Fishery Commission
GLFMP	Great Lakes Fish Monitoring Program
GLFMSP	Great Lakes Fish Monitoring and Surveillance Program
GLNPO	Great Lakes National Program Office
GLP	Good Laboratory Practice
GLRI	Great Lakes Restoration Initiative
GLWQA	Great Lakes Water Quality Agreement
IA	Interagency Agreement
IAG	Interagency Agreement (outdated term)
IDC	Initial Demonstration of Capabilities
IJC	International Joint Commission
LaMP	Lakewide Management Plan
LAN	Local Area Network
LMMB	Lake Michigan Mass Balance
LOY	Lake of the Year
MIRB	Monitoring, Indicators and Reporting Branch
MQOs	Measurement Quality Objectives
OEI	Office of Environmental Information
OW	Office of Water
PBDE	Polybrominated Diphenyl Ethers
PBT	Persistent Bioaccumulative Toxic Substance
PE	Performance Evaluation
PI	Principal Investigator
QA/QC	Quality Assurance/Quality Control
QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan
QSA	Quality System Audit
RAP	Remedial Action Plan
RFP	Request for Proposal

SOLEC	State of the Lakes Ecosystem Conference
SOP	Standard Operating Procedure
SOW	Statement or Scope of Work
TSA	Technical System Audit
US EPA	U.S. Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
USGS-BRD	United States Geological Survey – Biological Resource Division
USGS-GLSC	United States Geological Survey – Great Lakes Science Center

1.0 Quality Management and Organization

1.1 Introduction

The United States Environmental Protection Agency (US EPA) Chief Information Officer (CIO) policy 2105.0 (formerly US EPA Order 5360.1 A2) *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, May 2000, (http://www.epa.gov/irmpoli8/policies/21050.pdf) establishes policy and program requirements for the preparation and implementation of quality management systems (*Great Lakes National Program Office Quality Management Plan*, Revision 3, Draft [or current] at http://epa.gov/glnpo/qmp/index.html [Appendix A.7]). In support of this policy, US EPA requires each environmental program to develop a quality management plan (QMP). The QMP is management's statement of the process that will govern the quality assurance (QA) and quality control (QC) activities for a given program. The QMP defines the program's QA-related policies, areas of application, roles, responsibilities and authorities of staff, and the management and technical practices that ensure that environmental data used to support decisions are:

- Of adequate quality and usability for their intended purpose, and
- Where necessary, legally and scientifically defensible.

This document defines the Great Lakes Fish Monitoring and Surveillance Program's (GLFMSP) quality management system. The GLFMSP is an environmental program run by US EPA's Great Lakes National Program Office (GLNPO), designed to monitor contaminant trends in Great Lakes fish. GLNPO is a geographically focused office, whose mission is to lead and coordinate United States efforts to protect and restore the Great Lakes. This QMP is a management tool that describes how GLNPO will plan, implement, document, and assess the GLFMSP's ability to support its mission.

GLNPO management is responsible for ensuring that the QMP is implemented. In accordance with policies and procedures established under US EPA CIO policy 2105.0, (http://www.epa.gov/irmpoli8/policies/21050.pdf) Section 7.b, Program Office Directors and Senior Managers shall:

a) Ensure that all Program components comply fully with the requirements of the quality system policy;
b) Ensure that quality management is implemented as prescribed in the organization's approved QMP;
c) Ensure that the environmental data are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions;
d) Perform periodic assessments of the GLFMSP to determine the conformance of its mandatory quality system to its approved QMP and the effectiveness of its implementation;
e) Ensure that deficiencies highlighted in the assessments are appropriately addressed; and
f) Identify QA and QC training needs for all participants in the GLFMSP and provide for this training.

This QMP documents the GLFMSP's quality system to meet these requirements in fulfilling its mission. The QMP is organized in the following seven sections:

- **Section 1** continues with a description of the GLFMSP program, mission, organizational structure, and roles and responsibilities of GLFMSP participants;
- **Section 2** describes the components of GLFMSP's quality system, including a description of the tools used by GLNPO staff and other GLFMSP partners to implement the quality system;
- **Section 3** provides information regarding personnel qualifications and quality system training requirements;

- **Section 4** discusses GLFMSP's process for procuring items and services and ensuring suppliers provide items and services that are of known and documented quality and meet associated technical requirements;
- **Section 5** provides information on the control and maintenance of documents and records and the GLFMSP's process for managing information;
- **Section 6** provides a summary of the approach for GLFMSP systematic quality planning; and
- **Section 7** provides a description of GLFMSP's policies and procedures for assessing the environmental information collected, and procedures for responding to those assessments.

The GLFMSP's QMP is supported by the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8), which describes the QA/QC activities and procedures associated with collecting samples of fish tissue for the GLFMSP and Clarkson University's QAPP, *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP)* (Holsen *et al.*, 2012), which outlines the QA activities associated with the analytical component of this program (Appendix A.4).

This QMP is accompanied by a comprehensive CD made up of six appendices. This CD includes a complete library of current GLFMSP quality documentation (Appendix A), historical GLFMSP quality documentation (Appendix B), GLFMSP design documents and significant reports (Appendix C), GLFMSP significant events (Appendix D), GLFMSP collection information (i.e., collection grid maps, collector contact information, changes in collectors) (Appendix E), and a list of GLFMSP journal publications (Appendix F). These documents provide insight into the original design and operation of the GLFMSP. A table of contents for the appendices on this CD is included on pages 34-37 of this QMP.

In accordance with the instructions provided in CIO procedure 2105-P-01-0 this QMP is a dynamic document that is subject to change as the GLFMSP progresses. This QMP will be reviewed annually by the GLFMSP Manager to determine if revision is required. In addition, as the GLFMSP progresses in accordance with the continuous improvement philosophy, all changes to procedures described in this QMP will be reviewed by the GLNPO Quality Manager to determine if the changes significantly impact the quality objectives of the program. If changes are deemed to be significant, the QMP will be revised accordingly and distributed to the Monitoring, Indicators and Reporting Branch (MIRB) Chief, and the Office of Environmental Information's (OEI) Quality Staff.

1.2 Quality Management Policy, Goals, and Objectives

The GLFMSP's QMP is governed by the same principles guiding the quality management of GLNPO (*Great Lakes National Program Office Quality Management Plan*, Revision 3, Draft [or current] [Appendix A.7]). GLNPO's quality management policy focuses on four operating principles: assistance, flexibility, value-added, and continuous improvement. The GLFMSP operates under these same principles and works collaboratively with the quality team staff to ensure that the program will provide information of adequate quality to support environmental decisions.

The GLFMSP Manager, along with GLNPO QA staff, offers QA assistance to all participants in the GLFMSP to ensure adherence to the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8) during every phase of the program. GLFMSP partners responsible for fish collection and processing must adhere to the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8) during their sampling and processing procedures. Likewise the party responsible for the chemical analyses must adhere to the

approved quality documentation that they submit prior to GLFMSP sample analysis and the QA contractor must adhere to the approved quality documentation that they submit prior to providing support to the GLFMSP. The GLNPO quality program is flexible, in that all QA policies and requirements should provide added value to the GLFMSP, rather than inhibit the program through unnecessary restraint. Annual sample collection requires flexibility in its standard operating procedures (SOPs) due to the fact that in any given year, fish may not be present in sufficient abundance and collection location and/or sample number may be altered as a result. Quality documentation needs to be flexible enough to deal with these types of situations while maintaining value added to the GLFMSP through continuous improvement and strengthening of the program through tighter QA controls. The primary goals and objectives of the GLFMSP's QMP are to ensure that the program design and implementation are sufficient to meet the Program's overall objectives.

The GLFMSP plays an integral role in GLNPO's commitment and ability to protect the Great Lakes ecosystem. GLNPO must make decisions regarding the quality of the environment and the health of wildlife and humans. These decisions usually depend on qualitative and quantitative measurements derived from various data collection activities. The GLFMSP has produced one of the most valuable long-term contaminant trend datasets in the Great Lakes. Decision makers must be able to use this dataset with some level of confidence in order to make informed decisions. It is GLNPO's policy to ensure that collected information is of adequate quality for the intended use. This QMP ensures that data collected for the GLFMSP are of adequate quality to meet its goals and objectives of describing the health of the Great Lakes ecosystem both qualitatively and quantitatively. The GLFMSP quality management policy is implemented through a series of policies and practices that are described in Table 1.

Table 1. Policies and Practices

Policy	Practice
Allocation of appropriate resources	GLNPO management will allocate adequate resources to meet the quality system goals and requirements outlined in this QMP for the GLFMSP.
Inclusion of quality management in daily activities	It is GLFMSP policy that the quality system must be implemented in the daily activities of all GLFMSP partners. This policy is fostered through frequent interactions between the GLFMSP Manager and staff from the GLFMSP partners. Also, the GLFMSP Manager has been trained on the quality system philosophy, requirements, tools, and reference documents. In addition, GLNPO's Quality Manager is involved in a supporting role at the project level of the GLFMSP.
Systematic planning	The GLFMSP was originally designed to support a coordinated surveillance and monitoring program between the United States and Canada following the Great Lakes Water Quality Agreement. Fish were considered to be excellent integrators of aquatic ecosystems and thus could be used as indicators of overall ecosystem health. At the time that the GLFMSP was planned, very little data existed to help with the planning of this long-term environmental monitoring program. Using the best available data, GLNPO and U.S. Fish and Wildlife Service (USFWS) scientists mapped out the program objectives and strategy. As the program evolved and other objectives were added, the planning changed accordingly. These changes are documented in S*ignificant Events of the Great Lakes Fish Monitoring and Surveillance Program* (see Appendix D.1).
Quality system documentation	The GLFMSP has the appropriate quality system documentation in place: 1) a QAPP submitted to GLNPO by Clarkson University: *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP)* (Holsen *et al.*, 2012) (Appendix A.4), and 2) a QAPP submitted to GLNPO by the QA contractor: *Quality Assurance Project Plan for CSC Support to the Great Lakes Fish Monitoring and Surveillance Program* (CSC, 2011) (Appendix A.2).

Policy	Practice
Provision of quality training	The GLFMSP Manager is trained on the US EPA quality system requirements by GLNPO QA staff and has access to available quality implementation tools and reference and guidance documents. GLFMSP grantees that are performing the laboratory analyses are required to submit a QAPP outlining their quality procedures, and to participate with GLNPO QA staff during periodic audits to ensure that quality procedures are being followed. GLFMSP partners involved in fish collection and processing are required to follow the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8), and are reminded about proper collection procedures through a Sampler Information Packet and SOP released to them each fall before collection begins. GLNPO QA staff may conduct periodic site visits during the fall collection to ensure adherence to quality procedures.

1.3 Program Description

The GLFMSP is designed to examine the health of fish and fish-consuming wildlife through trend analysis, improve understanding of contaminant cycling throughout food webs in the Great Lakes, and screen for emerging chemicals in fish tissue to help identify new chemicals for future trend analysis.

The overall goals of the GLFMSP include:

- Monitoring temporal trends in bioaccumulative organic chemicals in the Great Lakes using top predator fish as biomonitors,
- Gathering information regarding the contaminant cycling throughout food webs in the Great Lakes, and
- Providing information on new compounds of concern entering the lakes ecosystem.

The GLFMSP has evolved over time, with the number of lakes, sampling locations, species, and contaminants expanding as resources allowed and scientific knowledge demanded. A list of past and present field sampling teams and a table of changes in analytical methods, analytes, laboratories and participants are listed in Appendix E. A summarized list of GLFMSP significant events, including changes in sampling, laboratories, and methods can be found in Appendix D.1.

Table 2 provides a brief history of the GLFMSP. For a more detailed history of the GLFMSP and changes to the Program, refer to the accompanying comprehensive CD (all included appendices). Appendix A contains all current GLFMSP quality documentation and Appendix B contains historical GLFMSP quality documentation. Appendix C contains GLFMSP program design documents and significant reports.

Table 2. GLFMSP History

Date	Event
Mid 1960s	U.S. Geological Survey Great Lakes Science Center (USGS-GLSC) (formerly known as U.S. Fish and Wildlife Service Great Lakes Fishery Laboratory) begins monitoring fish in Lake Michigan to measure the contaminant levels of various organic substances in lake trout in the Great Lakes ecosystem.
1977	USGS-GLSC collaborates with US EPA GLNPO to form the Great Lakes Fish Monitoring Program (GLFMP) to monitor top predator fish in the Great Lakes. The original study design is modified to generate more data by including additional species, sampling locations and contaminants. Through this cooperative agreement, a partnership is formed, with USGS collecting and processing the fish, and US EPA funding the analyses.
Early 1980s	GLFMP is expanded to include sport fish (coho and chinook salmon) to directly link the condition of the Great Lakes to the health of it users. Each Great Lakes State collects 15 fillets from Coho or Chinook salmon at designated sites. The Great Lakes States and the U.S. Food and Drug Administration (USFDA) become additional partners, with the States voluntarily collecting sport fish and the USFDA processing and analyzing the samples for toxic chemicals.
1998	USFDA withdraws from the cooperative agreement to analyze contaminants in sport fish. GLNPO maintains and operates the analysis of sport fish.
2003	USGS-GLSC discontinues cooperative agreement to analyze contaminants in whole fish, leaving GLNPO as the sole supporter of the program, both financially and through staff support.
2005	A program review sponsored by the US EPA occurred. The program review included an overview of the history of the GLFMP, current sampling plan, historical record of target analytes and data management, current program, Quality Management Program data storage, stakeholder use of GLFMP data, and technical charge. The GLFMP review panel made recommendations for consideration by GLNPO to help revise and enhance the GLMFP to better fit with current environmental conditions and better serve stakeholders.
2007	A peer review is conducted on the GLFMP to enhance the quality and validity of the program and ensure that the data generated under the program are statistically sound and representative of the current environment.
2009	In response to suggestions provided in peer review and careful assessment by GLNPO Management, Sport Fish Monitoring is eliminated from the GLFMP. The Emerging Chemical Surveillance Program is added to the GLFMP. The program name changes from GLFMP to Great Lakes Fish Monitoring and Surveillance Program (GLFMSP).
2010	Great Lakes Restoration Initiative establishes a task force of 11 federal agencies to devise and implement an action plan to proactively rehabilitate the Great Lakes. This task force identifies goals, objectives, and specific actions addressing each of five focus areas including the identification of toxic substances with an emphasis on their impact on ecosystems and the entire food web.
2011	In response to a Request for Proposals, Lake of the Year monitoring is proposed by Clarkson University's Principal Investigator and accepted. The CSMI/Special Studies Program is added to the GLFMSP.

The program is currently implemented by GLNPO with cooperation from the selected federal or local agencies, Great Lake states, and Native American Tribes. The present design of the GLFMSP includes three programs:

1. The Open Lakes Trend Base Monitoring Program (hereafter referred to as the "Base Monitoring Program"),
2. The Emerging Chemical Surveillance Program, and
3. The Cooperative Science and Monitoring Initiative (CSMI) / Special Studies Program

More information about these programs is provided in Section 1.3.1.

Over the life of the GLFMSP, a wide variety of metals and organic chemicals have been analyzed in fish samples collected in the Great Lakes Basin. The list of analytes has changed in response to both budgetary constraints and information about new and emerging contaminants. The current list of analytes of interest that are monitored on an annual basis and a list of emerging contaminants that are screened for are listed in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

1.3.1 Program Elements

The GLFMSP consists of the Base Monitoring Program, the Emerging Chemical Surveillance Program, and the CSMI/ Special Studies Program. These programs assist the GLFMSP in achieving its overall goals of (1) monitoring temporal trends in bioaccumulative organic chemicals in the Great Lakes using top predator fish as biomonitors, (2) gathering information regarding the contaminant cycling throughout food webs in the Great Lakes, and (3) providing information on new compounds of concern entering the lakes ecosystem.

The GLFMSP uses QAPPs for sample collection, preparation, and analysis to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. Because the GLFMSP is a continuing program, aspects of the GLFMSP are not static and evolve over time. As changes are made to the Program, they are documented in the appropriate QAPP.

Base Monitoring Program

The Base Monitoring Program is directed at monitoring the health of the Great Lakes ecosystem, using whole top predator fish as biomonitors (lake trout and walleye), for select contaminants to determine general trends and to provide support to the research community and the public through collection of high quality data using identified and approved methodology. These data also can be used to assess the risks of such contaminants on the health of this important fishery, and on wildlife that consume them. The Base Monitoring Program involves collection and analysis of predatory fish from all five Great Lakes on an annual basis, with slight differences in design during even and odd years. During odd years, lake trout (*Salvelinus namaycush*) in the size range of 600 mm to 700 mm will be collected in all five lakes. During even years, lake trout in the size ranges of 600 mm to 700 mm will be collected from four of the five lakes (Huron, Michigan, Ontario, and Superior) and walleye (*Stizostedion vitreum*) in the size range of 400 mm to 500 mm will be collected from Lake Erie. The GLFMSP organizes collections through cooperative agreements with other agencies or by purchasing predatory fish. Composites of each species, consisting of five individual fish, are analyzed for contaminants. The number of fish collected for the GLFMSP may vary from year to year due to unforeseen circumstances when collecting live fish. When fewer than the target number of composites are collected at a site for the Base Monitoring Program, then fewer than the target number of composites are analyzed, while keeping the number of fish per composite constant at five in order to maintain consistency in data at the individual composite level. An alternative approach may be considered if the number of fish collected is significantly lower than the target. Variability in the data should be taken into account when making final decisions.

Because this part of the program was designed to assess the overall effects of toxic chemicals on fish, whole fish are used for analysis, including parts not routinely eaten by humans such as liver and bones. The pollutants being measured meet three standards:

1. Continuity of testing, that is, the pollutants tested in the past were to be tested in the future,
2. The specific analysis techniques needed to be comparable to those used in the past, to preserve continuity, and
3. The specific pollutants (and their precursor or breakdown products) needed to be known or expected to be found in the open lakes.

The lake trout and walleye collected for the Base Monitoring Program are supplemented with control fish collected from inland lakes as designated by the Principal Investigator (PI). Comparing concentrations in these control fish to the Great Lakes fish helps determine sources of the compounds that are identified and the relative importance of atmospheric deposition.

The goals of the Base Monitoring Program include:

- Provide an indication of environmental quality,
- Identify contaminant levels in fish and their trends,
- Assess the impact of regulatory controls on whole lake conditions,
- Provide an early warning for new contaminants,
- Identify potential harm to fish stocks, and
- Identify transboundary contamination.

Detailed collection and site information for the GLFMSP Base Monitoring Program is located in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

Emerging Chemical Surveillance Program

The Emerging Chemical Surveillance Program is directed at screening for emerging chemicals in fish tissue according to their persistent, bioaccumulative, and/or toxic chemical properties. This program utilizes samples collected for the Base Monitoring Program and the CSMI/Special Studies Program to determine the presence of Contaminants of Emerging Concern (CEC), identify and guide State and Federal monitoring programs in the development of their analyte lists and priority setting, and to incorporate emerging CECs into the routine analyte list for the Base Monitoring Program and the CSMI/Special Studies Program. Identification of CECs is accomplished through two methods. The first method involves performing a detailed “Full Scan” analysis of Great Lakes Fish by screening for a set of previously identified contaminants in composite samples and analyzing extracts for previously unidentified peaks (non-legacy contaminants). The second method involves working from the US EPA sponsored *Potential Emerging Contaminant List* developed by Muir and Howard (*Howard & Muir, 2010)*. This list is based on high and medium production volume chemicals in the United States and Canada. Retrospective analysis may be conducted upon archived samples if a CEC is identified.

The goals of the Emerging Chemical Surveillance Program are to:

- Screen for a set of previously identified CECs,
- Determine the presence of CECs,
- Identify and guide State and Federal monitoring programs in the development of their analyte lists and priority setting, and

- Incorporate CECs into the routine analyte list for the Base Monitoring Program and the CSMI/Special Studies Program.

CSMI / Special Studies Program

The Cooperative Science and Monitoring Initiative (CSMI) was established by the Binational Executive committee (BEC) to address greater coordination of science and monitoring activities in the Great Lakes Basin pursuant to the obligations under the Great Lakes Water Quality Agreement (GLWQA).

The CSMI is a forum and a process to foster and coordinate collaboration for binational monitoring and research to meet key Lakewide Management Plan (LaMP) information needs, as well as support other science needs under the GLWQA (such as science needs of the Great Lakes Binational Toxics Strategy [BTS], Great Lakes Fishery Commission [GLFC], and the State of the Lakes Ecosystem Conference [SOLEC]). CSMI recognizes a five year rotational cycle of research and monitoring on the Great Lakes, in which science activities address one of the Great Lakes each year, but accommodate multiple lake activities simultaneously when necessary and practical. Within the five year rotational cycle, years one and two involve identification of priorities for collaboration and planning, year three involves intensive field activities, year four involves analysis and data work-up, and year five involves synthesis and communicating out to partners such as the Binational Executive Committee (BEC), the LaMP, and the public. In any given year, each lake is at a different stage in the cycle.

The GLFMSP participates in the CSMI through additional sample collection efforts and analyses as identified by the PI when funding is available.

The Great Lakes Restoration Initiative (GLRI) allowed for the inclusion of special studies in the five year award for the GLFMSP beginning in 2010. The current PI proposed to incorporate the CSMI into the GLFMSP through these special studies by conducting Lake of the Year (LOY) monitoring to improve our understanding of contaminant cycling throughout food webs in the Great Lakes by expanding research efforts in one lake each year. The LOY is chosen based on the schedule proposed by the CSMI.

The PI's proposal was accepted and in 2011 the CSMI/Special Studies Program was added to the GLFMSP to incorporate LOY monitoring. Unless otherwise designated, CSMI/Special Studies Program collections occur at the same locations in each lake as Base Monitoring Program collections.

CSMI/Special Studies Program collection efforts and analyses help build an understanding of the biological structure and composition of food webs which is important for understanding the flow of energy, nutrients, and ultimately contaminants through ecosystems. CSMI/Special Studies Program collection efforts include the collection of forage fish and the collection of fish and their associated eggs and stomach contents from two locations within the LOY. The purpose of collection of stomach contents is to assist in the evaluation of the movement of contaminants in complex Great Lakes food webs. This requires data on pollutant concentrations and fluxes (diet) for the top predator and the prey species at the supporting lower trophic levels. The eventual body burden of contaminants in predator fish depends on the feeding preferences and food availability at lower trophic levels and the contaminant burden of each prey species. The purposes of the collection and analysis of contaminant levels in individual fish and eggs are to evaluate the relationship of parent-egg contaminant levels, potentially identify new emerging contaminants, assess critical contaminant trends, and support lake-wide management plans. The CSMI/Special Studies Program also includes the collection of benthic invertebrates, phytoplankton, zooplankton and water samples from two locations within the LOY.

Because CSMI/Special Studies Program collection efforts and analyses are temporary and issued on a periodic basis, limited quality information is available for them. When possible, SOPs and QAPPs for additional sample collection and analysis are provided.

The goal of the CSMI/Special Studies Program is to gather information regarding the contaminant cycling throughout food webs in the Great Lakes.

Detailed collection and site information for the CSMI/Special Studies Program is located in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

1.3.2 Mission

The GLFMSP's mission is to support GLNPO's goal to restore chemical integrity to the Great Lakes Ecosystem by reducing toxic substances, with an emphasis on persistent bioaccumulative toxic substances (PBTs), so that all organisms are protected. Over time, these substances will be virtually eliminated.

The GLFMSP overall goals include:

- Monitoring temporal trends in bioaccumulative organic chemicals in the Great Lakes using top predator fish as biomonitors,
- Gathering information regarding the contaminant cycling throughout food webs in the Great Lakes, and
- Providing information on new compounds of concern entering the lakes ecosystem.

As a planning and assessment tool, the GLFMSP measures the overall success of bans, restrictions and other remedial actions to control lake pollution. It has also provided information on new toxic compounds entering the lakes' ecosystem. These objectives are accomplished by a systematic program of harvesting and analyzing fish and other organisms in the Great Lakes food web to ascertain the level of toxic pollutants in fish tissue.

Accomplishing the Mission

The GLFMSP was originally designed in the late 1970s to provide indicators of the health of the Great Lakes Ecosystem. At its inception, sampling and analyses for the GLFMSP were conducted by numerous state and federal agencies and coordinated by GLNPO, and results were peer-reviewed, reported to public authorities, and published in scientific journals.

The original design of this program (i.e., what is now the Base Monitoring Program) specified the monitoring of contaminant trends in the open waters of the Great Lakes (using fish as biomonitors), and assessing the overall effects of toxics on fish and fish consuming wildlife. These whole fish include parts that humans do not eat, but that wildlife consume. Thus, the program that was initially designed in the late 1970s was perfect for answering the bigger ecosystem health question, but was difficult to relate directly to human health. In general, an improvement in ecosystem health is representative of improving human health. However, data collected for the Base Monitoring Program have never been used to directly assess human health and have not been used in fish consumption advisories.

The program design designated the collection and analyses of lake trout from each of the Great Lakes (and walleye in Lake Erie) in the fall of the year, using fish of similar size to reduce the impact of size variation on contaminant trend data. Size was used as a surrogate for age, therefore fish in a narrow size range were targeted each year. Fish samples were collected and analyzed for several different contaminants, including PCBs, toxaphene, chlordanes, nonachlors, and other organochlorine compounds.

In the 1980s, the Sport Fish Monitoring Program was added to the GLFMSP in an attempt to address human health issues more directly. The majority of the data collected for this program were not robust enough to detect any significant trend. The inclusion of sport fish monitoring, however, did provide a snapshot of contaminant concentrations across the Great Lakes in fish of consistent age, complementing the size-based data collected in the open lakes component. The Sport Fish Monitoring Program provided for the collection of skin-on fillets from coho or chinook salmon (or rainbow trout, if neither was available) by the Great Lakes States. Fish samples were then analyzed for several different contaminants, including PCBs, toxaphene, chlordanes, nonachlors, and other organochlorine compounds. The Sport Fish Monitoring Program was later eliminated from the GLFMSP in response to suggestion provided in a peer review and careful assessment by GLNPO Management.

The GLFMSP has also played a crucial role in the identification of newer or "emerging" contaminants in the Great Lakes prior to becoming widespread and toxic in the environment. This part of the program was initially addressed by the Emerging Problems in Harbors and Tributaries Program. Following the discontinuation of this program, emerging contaminants were addressed using fish collected for the Base Monitoring and Sport Fish Monitoring Programs. The 1998 GLFMSP Request for Proposal (RFP) for the Base Monitoring Program and Sport Fish Monitoring Program included an emerging contaminants component. The PI awarded the grant for 1999–2003 took the most contaminated composite of each species from the lower three Great Lakes (Michigan, Erie, Ontario) from each year and examined the extracts for all halogenated compounds that could be detected, and identified them. Historically, the contaminants of concern have been found in higher concentrations in the lower lakes and so it seems more likely to find emerging contaminants in these samples.

In addition, full scans for a variety of contaminants were conducted by the GLFMSP PI and US EPA GLNPO following the Workshop on Identifying Emerging Contaminants for Fish Contaminant Monitoring Programs (Appendix B.8) in the spring of 2001. It was well known at the time that several emerging contaminants were being found throughout the environment, and the GLFMSP brought in five experts to present their most recent research on the presence and prevalence of emerging contaminants. The goals of the workshop were to 1) provide scientific input to US EPA and the states on what contaminants of present or emerging concern should be included in the GLFMSP and 2) provide scientific guidance on how to identify or anticipate potential contaminants of concern in fish tissue in the future. The overall purpose of the workshop was to provide a mechanism for improving and updating the list of contaminants currently considered in the GLFMSP. Following the Workshop, several "new" chemicals were added to the routine monitoring list, and several others were chosen to be measured qualitatively in a few of the most contaminated composites.

Many partner agencies continued to participate in pieces of the GLFMSP. However, following the withdrawal of USGS-BRD from the cooperative agreement with GLNPO (*USEPA/GLNPO Cooperative Agreement Withdrawal Memo)*, (Appendix C.13), GLNPO took on a much larger role in the management of the GLFMSP. Because the GLFMSP assesses ecosystem health over time and previously assessed human health over time, it is crucial that the data be comparable from one year to the next. Strict QC procedures are in place and will be discussed further in Section 2 of this QMP.

In 2005, a new RFP was issued, describing a slightly different approach to the analyses of emerging contaminants. The GLFMSP grant was issued for five years, and the PI was expected to conduct one Extended Program year over the course of five years, to look for specified emerging contaminants. Of the emerging contaminants added to the routine monitoring list following the 2001 conference, only PBDEs, mercury, and PCDD/Fs continue to be analyzed along with the routine samples.

In 2009, the Emerging Chemical Surveillance Program was added to the GLFMSP. This program is directed at screening for emerging chemicals in fish tissue according to their persistent, bioaccumulative, and/or toxic

chemical properties. This program utilizes samples collected for the Base Monitoring Program to determine the presence of Contaminants of Emerging Concern (CEC), identify and guide State and Federal monitoring programs in the development of their analyte lists and priority setting, and to incorporate emerging CECs into the routine analyte list for the Base Monitoring Program.

In 2010, the GLRI allowed for the inclusion of special studies in the five year award for the GLFMSP beginning in 2010. In response to an RFP, the current PI proposed to incorporate the CSMI into the GLFMSP through these special studies by conducting Lake of the Year (LOY) monitoring to improve our understanding of contaminant cycling throughout food webs in the Great Lakes by expanding research efforts in one lake each year. The PI's proposal was accepted and in 2011 the CSMI/Special Studies Program was added to the GLFMSP. This program allows the GLFMSP to gather information regarding the contaminant cycling throughout food webs in the Great Lakes. The Emerging Chemical Surveillance Program now utilizes samples collected for the CSMI/Special Studies Program in addition samples collected for the Base Monitoring Program to determine the presence of CECs, and identify and guide State and Federal monitoring programs in the development of their analyte lists and priority setting, and to incorporate emerging CECs into the routine analyte list for the Base Monitoring Program and the CSMI/Special Studies Program.

The GLFMSP has evolved greatly over the course of its existence and its flexibility is one of the many factors that have allowed it to stay relevant for such a long period of time. The continued success of the program is based on the overall structure and organization of GLNPO. This includes its communication network and working relationships with the eight Great Lakes states and the participating Tribal Nations. Cooperation among the States and Tribes, including access to a database of geographically and historically dispersed information on pollution trends, and the application of sound scientific procedures to critical public policy questions also contribute to the success of the GLFMSP.

Setting Goals to Accomplish the Mission

The GLFMSP Manager meets with the MIRB Chief at a minimum of twice a year during performance evaluations (PEs) to review and assess progress, identify goals for the coming year and outline technical activities to meet those goals. These activities typically include:

- Coordination between GLFMSP partners,
- Review and assessment of data collected,
- Development of environmental indicators,
- Development of reports/publications,
- Participation in conferences, sometimes as invited speaker,
- Binational coordination,
- GLFMSP Manager management of GLFMSP grantees,
- Website maintenance of GLFMSP information, and
- Ensuring that GLFMSP meets quality guidelines.

Additional activities may include:

- Development and release of RFPs,
- Organization of proposal reviews,
- Development of program QAPPs and QMPs,
- Organization of program peer review,
- Review of program QAPPs, and
- Quality system visits/audits.

1.4 Organization, Roles, and Responsibilities

Project participants and their roles and responsibilities for GLFMSP are provided below. An organizational chart is provided in Figure 1.

Director of the Great Lakes National Program Office

The **GLNPO Director**, Christopher Korleski, is responsible for providing financial and staff resources necessary to meet project objectives and implement the requirements of the GLFMSP. The Director is responsible for establishing GLNPO quality policy and resolving related issues, which are identified through GLNPO QA staff and study participants. Further information on the general roles and responsibilities for the GLNPO Director can be found in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current) (Appendix A.7).

Monitoring, Indicators and Reporting Branch Chief

The **Chief** of GLNPO's MIRB, Paul Horvatin, reports directly to the GLNPO Director and is responsible for providing overall direction concerning all aspects of the GLFMSP. Further information on the general roles and responsibilities for the GLNPO Branch Chiefs can be found in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current) (Appendix A.7).

GLNPO Quality Manager

The **GLNPO Quality Manager**, Louis Blume, is responsible for reviewing and approving all QAPPs and reports directly to the MIRB Chief. Additional GLNPO Quality Manager responsibilities regarding GLFMSP include the following:

- Reviewing and evaluating field procedures,
- Conducting external performance and system audits of the procedures, and
- Participating in Agency QA reviews of the study.

Further information on the general roles and responsibilities for the GLNPO Quality Manager can be found in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current) (Appendix A.7).

GLFMSP Manager

The **GLFMSP Manager**, Elizabeth Murphy, reports directly to the MIRB Chief and is responsible for supervising the assigned project participants. Additional GLFMSP Manager responsibilities include the following:

- Providing oversight for development of study design,
- Ensuring adherence to study design and accomplishment of project objectives,
- Reviewing and approving the project work plan, QAPP, and other materials developed to support the project,
- Coordinating with contractors, grantees, and US EPA Regions/States/Tribes to ensure technical quality and contract adherence, and

- Maintaining all official copies of GLFMSP documents and materials.

Further information on the general roles and responsibilities for the GLFMSP Manager can be found in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current) (Appendix A.7) under the topic of "Project Officers."

GLFMSP Principal Investigator

The **GLFMSP PI**, Thomas Holsen of Clarkson University, is responsible for adhering to guidance and protocol specified in the quality system documentation when carrying out tasks under the GLFMSP. Further information on the general roles and responsibilities for GLNPO PIs can be found in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current) (Appendix A.7).

Thomas Holsen serves as the current PI providing analytical and technical support and will continue to do so through the 2015 research year. Details regarding this component of the project can be found in the QAPP submitted to GLNPO by Thomas Holsen, *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP)*(Holsen *et al.*, 2012) (Appendix A.4).

The QAPP for analysis of tissue samples prior to 2004 can be found in *Trends in Great Lakes Fish Contaminants Quality Assurance Project Plan* (Swackhamer, 2004) (Appendix B.9) submitted to GLNPO by Deb Swackhamer of the University of Minnesota who served as PI from 1999-2003.

GLNPO Great Lakes Environmental Database Manager

GLNPO's **Great Lakes Environmental Database (GLENDA) Manager**, Kenneth Klewin, maintains the GLNPO database, GLENDA. GLENDA is the environmental database developed for GLNPO during the Lake Michigan Mass Balance (LMMB) study to house its environmental monitoring data. The GLENDA Manager is responsible for maintaining the integrity of environmental data housed in GLENDA.

Field Sampling Teams

Field sampling teams are selected by GLNPO and can include the following:

- State personnel such as field biologists or fisheries biologists,
- Federal agencies,
- Native American Tribes,
- Commercial fisherman, and
- Contracted field staff (including subcontracted organizations).

Field sampling teams are selected by GLNPO each year prior to the sampling event. A field sampling team leader is identified as the primary contact for study implementation. Sample collection personnel are responsible for performing fieldwork, including: collection, preparation, shipment of fish tissue samples, and completion of field sampling records. The field sampling teams must perform all work in adherence with the GLFMSP work plan and the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). Additional information on the roles and responsibilities of the field sampling teams are provided in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

QA Contractor

The QA contractor is responsible for coordinating with field samplers to create a schedule for shipping sampling

supplies. The QA contractor creates sampling kits and shipping kits and ships them along with coolers to the field sampling teams. The QA contractor also updates and provides the field sampling teams with hardcopy versions of the field recording form and chain-of-custody record, SOPs, and fish sample identification labels on an annual basis. QA contractor staff arrange for the shipment of samples between the field sampling teams, homogenization laboratory, and analytical laboratory. The QA contractor annually reviews and determines the homogenization laboratory and coordinates homogenization services support to the GLFMSP through a purchase order (PO) with the homogenization laboratory.

The QA contractor processes and formats the field data submitted by field sampling teams to the GLENDA reporting standard, conducts checks to ensure that all necessary information has been provided, and seeks to resolve any discrepancies. The QA contractor also enters data provided by the homogenization laboratory into the GLENDA files for the applicable sampling year and conducts a check on the data to ensure accuracy of data already provided in the GLENDA files. The QA contractor seeks to resolve any discrepancies in the data. Data assessments also are performed on laboratory-submitted data, and focus on data completeness, and data consistency. Data completeness checks are performed by comparing the field and laboratory data to identify any missing or non-unique sample analyses, while data consistency checks verify that the data correctly follow the GLENDA standard.

Additional information on the roles and responsibilities of the QA contractor are provided in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). The QA contractor has been Computer Sciences Corporation (CSC) since 2003. All support provided to the GLFMSP by CSC is done according to procedures described in the *Quality Assurance Project Plan for CSC Support to the Great Lake Fish Monitoring and Surveillance Program* (Appendix A.2).

Homogenization Laboratory

Field sampling teams send fish samples to the homogenization laboratory. The homogenization laboratory records physical measurements, collects coded wire tags, scales, and/or otoliths when applicable, records any abnormalities (e.g., tumors, fins missing, wounds, etc.), collects samples for aging purposes (e.g., scales, otoliths, and coded wire tags) prepares composites of the samples, homogenizes the samples, and prepares mega-composites of the samples. Each mega-composite includes tissue from all “regular” composites from a single site. The homogenization laboratory also prepares aliquots from composites, individual samples, and mega-composites and sends them to an archival facility and the analytical laboratory. Homogenization services were provided by AXYS Analytical in Sydney, British Columbia, Canada between 2003 and 2010. In 2011, Aquatec Biological Sciences, Inc. in Williston, Vermont, began providing homogenization services.

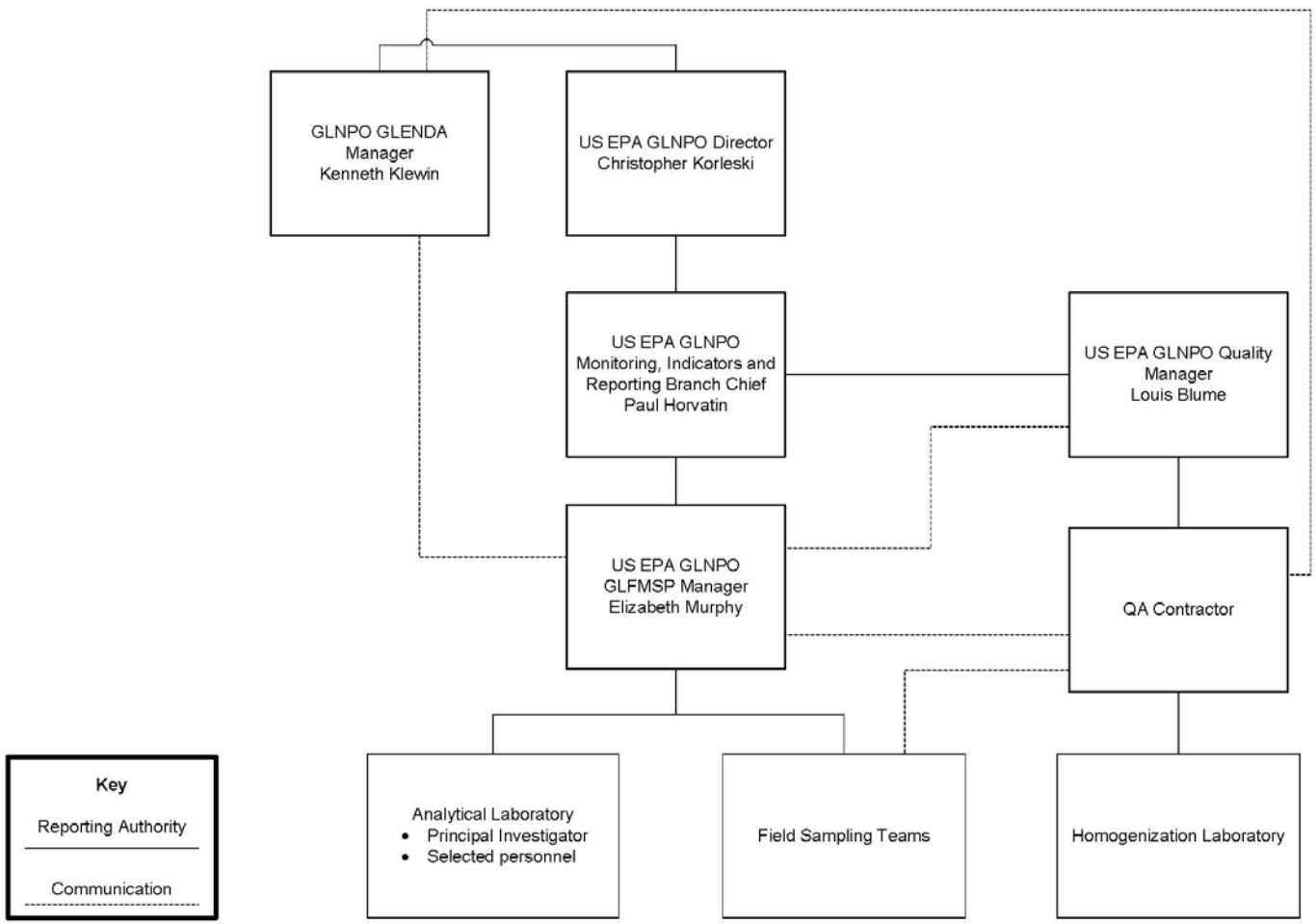
The laboratory must adhere to the sample receipt requirements, sample preparation and physical data collection requirements, homogenization requirements, aliquot creation requirements, sampling handling and custody requirements, and QC requirements outlined in their Statement of Work (SOW) as determined through the PO with the QA contractor. The SOW for the homogenization laboratory is updated and reviewed annually by the QA contractor. The homogenization lab must have approved SOPs in place prior to beginning work. The current homogenization laboratory’s SOP for support to the GLFMSP can be found in Appendix A.1. Any deviations from the SOPs should be approved prior to implementation by the GLFMSP Manager or if the deviation was unintentional, reported immediately to the GLFMSP Manager. Additional information on the roles and responsibilities of the homogenization laboratory are provided in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

Analytical Laboratory

Field sampling teams send some samples directly to the analytical laboratory. The majority of samples are sent to the analytical laboratory by the homogenization laboratory. Clarkson University was awarded chemical analysis of the GLFMSP tissue samples in 2004 following submissions and approval of quality documentation. Thomas Holsen serves as the PI providing analytical and technical support and will continue to do so through the 2015 research year. Details regarding this component of the project can be found in the QAPP submitted to GLNPO by Thomas Holsen: *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP)* (Holsen *et al.*, 2012) (Appendix A.4).

The QAPP for analysis of tissue samples prior to 2004 can be found in *Trends in Great Lakes Fish Contaminants Quality Assurance Project Plan* (Swackhamer, 2004) (Appendix B.9) submitted to GLNPO by Deb Swackhamer of the University of Minnesota who served as PI from 1999-2003.

Figure 1. Participants in the Great Lakes Fish Monitoring and Surveillance Program



2.0 Quality System Components

The GLFMSP must implement a quality management program that provides the management and technical practices to ensure that environmental information collected and used to support US EPA decisions are of adequate quality and usability for their intended purpose. The GLFMSP uses a wide variety of quality management practices and tools to implement its quality system including:

- GLFMSP QMP,
- Systematic quality planning,
- QAPPs,
- SOPs,
- Training,
- Coordination and meetings, and
- Quality assessments.

2.1 GLFMSP Quality Management Plan

This QMP serves to document the GLFMSP's quality system and also to communicate the quality system to all GLFMSP partners. The QMP is developed for use by the GLFMSP Manager and staff involved with the GLFMSP from other agencies or organizations. Ultimately this QMP assures all users of GLFMSP data that they are of high quality and can be used for environmental decision making. This QMP is approved by a GLNPO quality staff representative and the GLFMSP Manager.

2.2 Systematic Quality Planning

A crucial component of the quality system implemented for the GLFMSP is up-front systematic planning. Although projects can vary greatly in scope and importance, each should be started in essentially the same way: by determining the level of quality required and by planning accordingly. Consistent with GLNPO's graded approach, the level of quality required will be determined by evaluating the importance of the activity, available resources, the unique needs of the organization, and the consequences of potential decision errors. A systematic planning process is used to facilitate the planning of data collection activities. It asks the data user to focus their planning efforts by specifying: 1) the use of the data (the decision), 2) the decision criteria, and 3) an acceptable probability threshold for making an incorrect decision based on the data.

Systematic planning must be a normal part of the project planning process and must be accomplished based on cost-effectiveness and realistic capabilities of the measurement process. The process should:

- Establish a common language to be shared by decision makers, technical personnel, and statisticians in their discussion of program objectives and data quality,
- Provide a mechanism to pare down a multitude of objectives into major critical questions,
- Facilitate the development of clear statements of program objectives and constraints that will optimize data collection plans, and
- Provide a logical structure within which an iterative process of guidance, design, and feedback may be accomplished efficiently and cost effectively.

More information on GLFMSP quality planning is included in Section 6 of this QMP. The output of the systematic planning process for the GLFMSP can be found in the current version of the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). Further information on the general systematic planning process employed for GLNPO projects can be found in the current version of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft* (or current), Section 7 (Appendix A.7).

2.3 Quality System Documentation

US EPA quality policy requires every data collection activity to have written and approved quality system documentation (typically QAPPs) prior to the start of the collection. The purpose of the documentation is to specify the policies, organization, objectives, and the QA activities needed to achieve the project objectives. It is the responsibility of the GLFMSP Manager to adhere to this policy. GLNPO employs a checklist that can be used by the GLFMSP Manager and the Quality Manager to determine if formal quality system documentation is necessary for a given project. This checklist can be found in Appendix F of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7). If the GLFMSP Manager proceeds without approved quality system documentation, she is fully aware of the risks and assumes all responsibility. This risk should be taken only in extreme emergencies, which are not anticipated for GLFMSP. The GLFMSP Manager also bears the responsibility of providing copies of the approved quality system documentation to each individual who has a major responsibility in GLFMSP and explaining the elements of the quality system documentation to these individuals. If a QAPP is deemed to be required by the GLFMSP Manager and GLNPO Quality Manager, QAPPs are prepared, reviewed, and approved in accordance with US EPA QA/R-5, US EPA Requirements for QAPPs (Appendix G of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, [or current] [Appendix A.7]). US EPA QA/R-5 identifies and defines the 24 elements that must be addressed in all formal QAPPs; for some projects, only a subset of the 24 elements may be applicable. Further information on QAPP preparation, review, and approval can be found in the Section 2.3 of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7).

GLFMSP Quality System Documentation

GLNPO assumed QA responsibilities for the GLFMSP in 1992 and has maintained quality documentation since that date. Clarkson University was awarded chemical analysis of the GLFSMP in 2006 and again in 2010 following submission and approval of quality documentation: *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP)* (Holsen *et al.*, 2012) (Appendix A.4).

In 2012, US EPA GLNPO updated the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8), which describes the QA and QC activities and procedures associated with collecting samples of fish tissue for the GLFMSP. All States and other fish collection agencies are required to follow this QAPP when participating in fish collection procedures for the GLFMSP. Any deviations from documented fish collections procedures are documented by the GLFMSP Manager.

All support provided to the GLFMSP by the current QA contractor is conducted according to procedures described in the *Quality Assurance Project Plan for CSC Support to the Great Lake Fish Monitoring and Surveillance Program* (Appendix A.2).

2.4 Standard Operating Procedures

Good laboratory practices (GLPs) and good management of field sampling operations include the development and use of SOPs for all routinely used sampling, preparation, and analytical laboratory methods. SOPs facilitate comparability of data generated at different times, or by different field or laboratory staff. These protocols should be detailed enough so that someone else can reproduce results using the SOP (i.e., a journal article is usually not sufficient). Methods can be included in the quality system documentation either in the body of the document or as an appendix. If the referenced method is not followed precisely, addendums to the method must be included in the documentation that clearly identifies changes to the method, such that changes are obvious to any individual using the method. If an altered method is used for an extended period of time, the full method must be revised. A method cannot be revised during project implementation without the prior consent of the GLFMSP Manager. If the modification is accepted, it must be documented in a letter to the GLFMSP Manager and included in the next submitted report. It is the responsibility of the GLFMSP Manager to inform all relevant project participants of the protocol change.

In addition to QMPs, QAPPs, and SOPs, laboratories working with GLNPO should have a GLP document that is available for review during technical audits. These documents refer to the general practices that relate to the majority of measurements such as: facility and equipment maintenance, record keeping, chain of custody, reagent control, glassware cleaning, and general safety.

2.5 Training

Field Sampling Teams

The training for field collection crews is described in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). This QAPP is distributed to all collection teams prior to collection activities. Each field sampling team is required to have the experience and knowledge to perform all field activities. The GLFMSP Manager contacts all sampling personnel annually prior to collection to review appropriate collection procedures and to answer any potential questions.

QA Contractor

The QA contractor must demonstrate its ability to provide high quality support to the GLFMSP through submission of a QAPP. This QAPP must detail all relevant QA contractor staff training and certification.

Homogenization Laboratory

The laboratory performing the homogenization and archiving of samples must also demonstrate appropriate levels of expertise before receiving the samples through submission of a QAPP and SOPs to the QA contractor. The laboratory must adhere to the sample receipt requirements, sample preparation and physical data collection requirements, homogenization requirements, aliquot creation requirements, sampling handling and custody requirements, and QC requirements outlined in their SOW as determined through the PO with the QA contractor. The homogenization lab must have approved SOPs in place prior to beginning work. Any deviations from the SOPs should be approved prior to implementation by the GLFMSP Manager or if the deviation was unintentional, reported immediately to the GLFMSP Manager. The QA contractor may conduct audits on the homogenization laboratory to ensure that proper procedures are being followed and that all requirements are being met.

Analytical Laboratory

The analytical laboratory must demonstrate its ability to conduct high quality work and ensure the proper training of staff prior to receiving any analytical samples through submission of QAPPs, analysis of PE samples, and periodic visits from GLNPO QA staff.

2.6 Coordination and Meetings

Periodic Meetings with GLNPO Quality Manager and MIRB Chief

These meetings provide updates to the MIRB Chief on the progress of the quality control reviews of GLFMSP datasets. Meetings occur as necessary.

Monthly Conference Call between PI and GLFMSP Manager

A monthly GLFMSP conference call was established following the Program review conducted on February 7 and 8, 2005. These calls are held to identify progress in all areas of the GLFMSP, including homogenization, extraction, chemical analyses, data QA/QC, and database entry. When appropriate for the call content, these calls can also include the GLNPO QA staff and supporting contractor. These calls allow free discussion between those involved and can help to identify problems or bottlenecks associated with the data.

2.7 Quality Assessments

Quality systems audits (QSAs) are on-site evaluations by internal or external parties to determine if the organization is implementing a satisfactory quality management program. They are used to determine the adherence to the program, the effectiveness of the program, and the adequacy of allocated resources and personnel to achieve and ensure quality in all activities. Technical systems audits (TSAs) are qualitative on-site evaluations of any phases of an environmental data operation (e.g., sampling, preparation, analysis). These audits can be performed prior to or during the data collection activity, to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the quality system documentation. Because a TSA is most beneficial at the beginning of a project, GLNPO schedules audits at the initiation phase of an environmental data operation, when possible. GLNPO performs a QSA, site visit, or TSA for the most high-profile environmental data operations (i.e., those that support an important decision). The number and frequency are dependent on the length of the project, the importance of the project objectives, and the evaluations of prior audits.

More information on GLFMSP quality assessments is included in Section 7 of this QMP. The specifics of assessments (e.g., frequency) for the GLFMSP can be found in the current version of *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). Further information on environmental assessments employed for GLNPO projects can be found in the Section 9 of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7).

3.0 Personnel Training and Qualifications

The success of any quality management program ultimately lies with the personnel who implement the program on a daily basis. The GLNPO Quality Manager is responsible for ensuring that the GLFMSP Manager understands and implements the GLNPO's quality system while managing the GLFMSP. The GLFMSP Manager is required to complete the quality system training provided by GLNPO so that he or she understands and adheres to GLNPO's quality system. He or she should understand the philosophy of improving activities to provide the highest quality data in a cost-efficient manner. In addition to the GLFMSP Manager, all participants involved in the GLFMSP should adhere to the GLFMSP quality system.

Current GLFMSP quality documentation can be found in Appendix A and historic GLFMSP quality documentation can be found in Appendix B.

GLNPO Quality Manager Training

The GLNPO Quality Manager strictly adheres to the training requirements detailed in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7).

The GLNPO Quality Manager regularly attends national and, in some cases, international conferences and meetings on quality systems and the development of quality management materials and protocols relevant to GLNPO. The GLNPO Quality Manager will participate in training courses on quality management topics, such as data quality assessment and QAPP development. With this foundation, and with the GLNPO Quality Manager provision of training for GLNPO staff, this ensures that the GLFMSP Manager receives up-to-date training on a variety of QA subjects including US EPA's quality policy.

The GLNPO Quality Manager makes every effort to bring QA training to GLNPO personnel and its contractors and collaborators. For example, beginning in 2010, GLNPO, the Office of Water (OW), and Region 5 provided a series of training modules on quality management to foster awareness of US EPA's quality system and train US EPA staff and collaborators on quality implementation for US EPA-funded projects. These modules are designed to:

1) provide a source of standard quality management training for GLNPO, OW, and Region 5 personnel, as well as external collaborators and funded entities,
2) facilitate implementation of quality programs for projects, such as support to the GLRI, and
3) provide a knowledgebase for individuals who hold direct quality management responsibilities, as well as individuals responsible for conducting projects and ensuring quality is incorporated into those projects.

To date, fifteen training modules have been developed and held on-site at Region 5 headquarters and via webinar. They have attracted more than 1,800 attendees from a wide variety of organizations including US EPA Headquarters and Regions, six Great Lakes states, federal agencies, tribal nations, universities, contractors, and laboratories.

Additionally, GLNPO coordinates an annual GLRI Quality Technical Conference held in Chicago, Illinois. The GLNPO Quality Manager chairs the conference, with support from a designated Steering Committee that includes US EPA representatives from the OW, Region 2, Region 5, Office of Solid Waste and Emergency Response, and GLNPO, as well as QA contractor support. A primary goal of the GLRI Quality Technical Conference is to bring together GLRI Collaborators to facilitate implementation of quality practices for GLRI projects.

GLFMSP Manager Quality System Training

The MIRB Chief is responsible for ensuring that the GLFMSP Manager has the qualifications to do his or her job, including those related to the quality system. The MIRB Chief is responsible for discussing quality training needs with the GLFMSP Manager during the mid-year and annual personnel PEs. The GLFMSP Manager must complete the GLNPO Quality System Training for Project Officers and the Overview of GLNPO's Quality System every three years. Other training opportunities include QAPP Development and Auditing and Data Verification/Validation Techniques.

GLFMSP Grantee Quality System Training

The GLFMSP grantees are required to submit an approved QMP and/or QAPP before they begin work. The QMP and or QAPP must be approved by both the GLFMSP Manager and the GLNPO Quality Manager. In the QMP and QAPP, the grantees must demonstrate that their staff has the necessary training and experience needed to accomplish the work.

Field Sampling Team Quality System Training

The GLFMSP field sampling teams must use qualified and well-trained staff to perform their GLFMSP functions. Field sampling teams can consist of state personnel such as field biologists or fisheries biologists, federal agencies, Native American tribes, commercial fisherman, or contracted field staff (including subcontracted organizations). Field sampling teams are required to adhere to the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8) and appropriate fish collection SOPs (Appendix A of the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* [Appendix A.8]) to the best of their abilities. Field sampling team members are also welcome to participate in the GLNPO sponsored Quality System Training. A list of past and present field sampling teams is available in Appendix E.3.

QA Contractor

The QA contractor is required to submit an approved QAPP before they begin providing support to the GLFMSP. The QAPP must be approved by both the GLFMSP Manager and the GLNPO Quality Manager. In the QAPP, the QA contractor must demonstrate that their staff has the necessary training and experience needed to accomplish the work.

Homogenization Laboratory

The laboratory performing homogenization services in support of the GLFMSP is required to submit a QAPP and SOPs to the QA contractor prior to beginning work. In the QAPP and SOPs, the laboratory must demonstrate that their staff has the necessary training and experience needed to accomplish the work. The laboratory must adhere to all requirements outlined in their SOW as determined through the PO with the GLNPO QA contractor.

4.0 Procurement of Items and Services

The GLFMSP must ensure that procured items and services meet US EPA regulations, are delivered in a timely fashion, and are within GLNPO's specifications. The following sections describe the GLFMSP's procurement procedures.

It is GLNPO policy that quality system requirements be explicitly addressed when acquiring items or services for the GLFMSP. This policy applies to procurements such as contracts, as well as to cooperative agreements, partnership agreements, grants to institutions of higher education, and other non-profit organizations, Tribes, States, local governments, and interagency agreements (IAs). The following federal regulations contain sections relating to quality management or quality systems:

- 48 CFR Part 46. Quality Assurance – http://www.access.gpo.gov/nara/cfr/waisidx_10/48cfr46_10.html
- 40 CFR Part 30. Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations – http://www.access.gpo.gov/nara/cfr/waisidx_10/40cfr30_10.html
- 40 CFR Part 31. Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments – http://www.access.gpo.gov/nara/cfr/waisidx_10/40cfr31_10.html
- 40 CFR Part 35. State and Local Assistance – http://www.access.gpo.gov/nara/cfr/waisidx_10/40cfr35_10.html

4.1 Procurement of Items

The GLFMSP will utilize the services of the US EPA Region 5 Acquisition and Assistance Branch of the Resource Management Division for its procurement of items if necessary. Typically, the GLFMSP does not procure items, only services.

4.2 Procurement of Services

Contracts and assistance agreements, such as grants and IAs, are used by the GLFMSP to procure services (Appendix E.3).

The GLFMSP Manager maintains the assistance agreements for sample collection and chemical analysis of fish tissue. The GLNPO Quality Manager maintains the contract for GLFMSP QA support and homogenization activities.

4.2.1 Assistance Agreements

The GLFMSP uses extramural agreements to procure services when there is mutual benefit to GLNPO and the participating group from the arrangement. The two types of extramural agreements used in the GLFMSP include IAs with other agencies and cooperative assistance agreements with universities. These types of funding mechanisms are chosen because they allow for substantial involvement of GLNPO in the project. The GLFMSP issues a RFP every five years, unless otherwise determined by GLNPO, and adheres to US EPA's competition policy and the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7). Following proposal submission, the GLFMSP Manager conducts a proposal review that includes both internal GLNPO and external reviewers. The GLFMSP Manager presents the recommendation of the review team to the MIRB Chief for approval and the applicant is notified of the decision both electronically and via mail. The agreement is then implemented with the help of the US EPA Region 5

Acquisition and Assistance Branch of the Resource Management Division, which must approve all agreements before they are awarded.

The GLFMSP Manager will include any conditions for which project participants must adhere in the assistance agreement.

Sample Collection, Preparation, Homogenization, and Storage

The GLFMSP is responsible for sample collection, preparation, and homogenization.

The GLFMSP uses a combination of IAs, cooperative agreements, and amendments to pre-existing grants to fund fish collections and fish processing. Many collection entities support the GLFMSP through voluntary collection of samples at sites that are on their routine collection schedules and require minimal additional time and expense. Cooperative agreements have been drafted and put into place with these types of agencies. The GLFMSP has entered into assistance agreements or IAs with collection entities that are not able to take on the extra expense of time and / or money to collect GLFMSP samples. Fish sample preparation and homogenization is funded through the use of contracts and is discussed in Section 4.2.2.

USGS-GLSC has continued to archive samples at no cost to GLNPO following their withdrawal from the cooperative agreement in 2003. Samples collected from the 2004 sampling season to the present are archived at Microbac Laboratories in Baltimore, Maryland. Archiving is funded through the QA contractor and is discussed in Section 4.2.2.

Sample Analysis

The GLFMSP issues assistance agreements or IAs for the analyses of samples for the Base Monitoring Program and the Emerging Contaminant Surveillance Program. These agreements allowed for a more collaborative process and resulted in benefits for both parties. Fish analysis is currently funded through an assistance agreement with Clarkson University.

Because the GLFMSP assistance agreement for the chemical analyses involves an environmental collection activity, the GLFMSP Manager includes the required special conditions statement regarding quality systems as described in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7).

4.2.2 Contracts

A contract is used when GLNPO derives sole benefit from a particular product or service. The GLFMSP ensures that US EPA quality-related contracting policies, as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy, and the US EPA Contracts Management Manual (US EPA Order 1900 [EPA 1998]), are satisfied. This includes adhering to US EPA requirements regarding competitively bidding contracts, with certain exceptions (http://www.epa.gov/oam/ptod/posc.htm).

The GLFMSP utilizes existing contracts to fund fish sample collections, preparation, and homogenization. Through these contracts, the GLFMSP Manager ensures 1) the fish sample repository is adequately maintained and 2) the homogenization services are procured and managed properly.

All contracts utilized by the GLFMSP will follow the guidelines in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7) and include requirements for the provision of a QMP and QAPP, or other appropriate quality system documentation. The GLFMSP Manager is responsible for ensuring the presence of a well-defined SOW and for ensuring the presence of quality system documentation that includes reviews or audits.

5.0 Document Control, Records, and Information Management

The GLFMSP follows the procedures outlined in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7) for maintaining proper document control and records.

5.1 Management of Documents and Records

The history of document management for the GLFMSP is not well known prior to 1991 and because portions of the program were conducted voluntarily, partners were not bound by GLNPO quality requirements. Originally, all QA issues for the analytical portion of the Base Monitoring Program were the responsibility of the Region 5 Central Regional Laboratory and GLNPO does not have copies of these QAPPs readily available. However, details regarding strategic planning, objectives, methods and quality control can be found in several historical US EPA documents as well as published manuscripts in scientific journals (See Appendices B, C, & F). The fish processing, analysis, and archiving procedures conducted by USGS-BRD (originally the USFWS) are well documented in SOPs and can be found in Appendix B.4, B.6, and B.7. The nearshore program was conducted by the FDA until 1997, and they followed their own program's methodology and QAPPs (Appendix B.3).

The GLFMSP currently adheres to strict document and record management. The GLFMSP Manager is responsible for maintaining all documents and materials associated with the GLFMSP. Final reports, QAPPs, and other documents associated with the GLFMSP are stored as hard copies and soft-copies are maintained on GLNPO's local area network (LAN) site location (G:\ALL\QA).

5.2 Management of Information

The GLFMSP is unique compared to many environmental monitoring programs because of its long term data collection and analysis. Due to the 30+ year history of the GLFMSP, maintenance of data over time has changed hands and procedures many times. Presently, very strict protocols exist to govern the verification, storage, and release of data collected under the GLFMSP. This process was implemented in the fall of 2003 and affected all data beginning in the year 1999.

During the data verification and validation process, the PI submits the data to US EPA and the designated QA contractor in the GLENDA fish tissue reporting standard, which can be found at http://epa.gov/greatlakes/monitoring/data_proj/glenda/rptstds/index.html. The QA contractor then QA/QCs the data and sends the flagged dataset to the PI for correction. Each time this process occurs, a different number is assigned by the GLENDA Manager to the file to track changes. For example, a submission is marked with a 1 and so on. This process repeats until a dataset fully checked for completeness and consistency is established and the GLNPO GLENDA Manager uploads the finalized dataset to GLENDA after he or she conducts an additional

QA/AC of the dataset. All submissions from the PI are stored on the G drive, G:\DATA\Fish Data. The GLFMSP Manager approves each finalized dataset.

In addition to the GLENDA database, the GLFMSP manager has expressed a need to facilitate easy retrieval of sample results as well as summary data. In order to meet the GLFMSP Manager's needs, QA contractor staff are developing a Microsoft Access Database to store all historical and current GLFMSP data. In addition to being uploaded to GLENDA, each finalized dataset will be uploaded to the GLFMSP Microsoft Access Database by the QA Contractor.

All data requests are channeled to the GLFMSP Manager for response. Data requests will be tracked, including all contact information, so that any later changes made to GLENDA and the GLFMSP Microsoft Access Database can be forwarded to the appropriate people. In cases where GLENDA needs to be queried, the GLNPO GLENDA manager will be consulted.

5.3 Data Reporting

Data is released according to the *Great Lakes Fish Monitoring and Surveillance Program Data Release Guidelines* (Appendix C.10). The data produced by the GLFMSP are of high interest to the general public and to researchers and are available through a request to the GLFMSP Manager. Journal publications serve as the method for final data reporting. A list of publications using GLFMSP data is available in Appendix F.

The GLFMSP Manager will make a public announcement annually when data that have been checked for completeness and consistency are available in GLENDA and the GLFMSP Microsoft Access Database. Data will be available through a request to the GLFMSP Manager.

In addition to scientific publication, GLFMSP data are used in various governmental reporting venues and in annual reports, including the SOLEC report and the BTS semi-annual reporting. Examples of GLFMSP reporting can be found in Appendix F.1.

6.0 Quality Planning

The concept of the “quality cycle” was made popular by W. E. Deming in the 1980s. The GLFMSP’s quality system has translated Deming’s four components of: plan, do, check, and act, into:

- **Planning** projects with quality in mind
- **Implementing** the project according to plan and making revisions when needed to address unforeseen problems or changes
- **Evaluating** the quality of interim and final products against the planned goals
- **Incorporating lessons learned** into future activities

The GLFMSP’s quality system processes for addressing each of these components is addressed in Sections 6.1 through 6.4. **Documentation** is not considered a distinct phase in the quality system. It is an ongoing requirement that you must perform throughout all phases of your project. Indeed, it is often argued that if you did not document your quality management activities, you did not perform them. Because documentation is so important, please refer to Section 5 of this QMP and Sections 5 and 7.2 of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7), for more information. The GLFMSP follows the project planning and scoping process detailed within GLNPO’s QMP,

Great Lakes National Program Office Quality Management Plan, Revision 3, Draft, (or current) (Appendix A.7), Section 7.

6.1 Planning Quality

6.1.1 The Planning Process

It is US EPA policy that environmental data operations are planned using a systematic planning process that is based on the scientific method. The planning process is based on a common sense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources; the process, when implemented, is documented. Elements of a systematic planning approach include:

- Identifying and involving the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers),
- Describing the project goal, objectives, and questions and issues to be addressed,
- Identifying project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements),
- Identifying the type of data needed and how the data will be used to support the project's objectives,
- Determining the quantity of data needed and specification of performance criteria for measuring quality,
- Describing how, when, and where the data will be obtained (including existing data) and identifying any constraints on data collection,
- Specifying needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, PEs, etc.), and
- Describing how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria.

GLFMSP's quality system relies on systematic planning that is essential to managing quality, which is carried out by GLFMSP participants with extensive knowledge of the program. This ensures that the relevance of the project and activities undertaken result in data that has the level of quality needed for its intended purpose.

6.1.2 Planning Tools

The GLFMSP uses a variety of planning tools that help manage the quality of its supporting activities. These tools include quality and peer reviews, standardized forms, and a formal multi-step process used to derive qualitative and quantitative statements concerning data quality objectives for the project. These planning tools are employed by the GLFMSP in a systematic fashion.

Quality Review: Also known as peer input or peer consultation, this type of planning review refers to the involvement of technically qualified peers during the development of a work product and includes an open exchange of data, insights, and ideas. Peer input also is an effective tool during the assessment stage of the project and, therefore, is further described in Section 7.3 of this QMP.

Standardized Forms: The GLFMSP utilizes a variety of standardized forms and checklists to assist in ensuring information, data, and supporting activities are planned and documented efficiently and effectively including

(but not limited to) a field recording form, traffic reports, data reporting templates, etc.

Data Quality Objective Process: A formal, multi-step process described in US EPA QA/G-4, Guidance for the Data Quality Objective Process (US EPA, 2006) was developed as a systematic planning tool for environmental data collection. The process was originally developed around primary data collection activities and while it may be applicable to establishing objectives for secondary uses of data, it retains a focus on primary data collection. This process was used as a basis for developing the GLFMSP data quality objective. Refer to the *Great Lakes Fish Monitoring Program Data Quality Objective Revision Report* (Appendix B.1) and the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8) for more information on the program DQO and sampling design.

Formal Peer Review: US EPA has a formal Peer Review Policy, described in the US EPA Peer Review Handbook (3rd edition, US EPA/100/B-06/002). In accordance with this policy, the GLFMSP's quality system requires that Peer Review be incorporated into the planning process of its work products. This documented, critical review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the scientific or technical work product and of the documentation that supports this product. Refer to Section 7.4 of this QMP for more information.

6.2 Implementing Quality Management Activities

All GLFMSP participants (as described in Section 1.4) are responsible for implementing this QMP. There are numerous QAPPs supporting the GLFMSP and it is the GLFMSP Manager's responsibility to ensure that all QAPPs are kept up to date. All GLFMSP participants are responsible for implementing the QAPPs supporting the GLFMSP.

The GLFMSP Manager ensures the approved GLFMSP QAPP for Sample Collection Activities is disseminated and provided to the analytical and homogenization labs, field sampling teams, supporting contractors, the entire office at GLNPO, and to all program participants. This QAPP identifies the specific responsibilities for program participants as well as the quality activities and practices in place to develop and ensure the quality of the data produced. The QAPP outlines corrective actions should unanticipated problems occur including detailing how identified problems are identified, documented (including any deviations from the QAPP), and the steps taken to resolve the problems.

6.3 Evaluating the Results and Making Adjustments

Several of the evaluation tools are the same as those used to plan quality management activities (Section 6.1.2). For example, peer consultation and peer review are effective ways to obtain an independent assessment of the quality of data generated in the project or of the final work product. The point of the evaluation is not to cast blame for delays or other problems, but rather, to identify aspects of the project that posed problems and build on that knowledge when designing future projects.

Other tools are specifically designed to facilitate the evaluation phase of the quality system. These include data validation, data quality assessment, technical system reviews or assessments, annual program reviews, and quality system assessments. These evaluations described in GLNPO's QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) (Appendix A.7), along with recommended corrective strategies, may be carried out GLFMSP participants.

6.4 Quality Improvement

One goal of this quality system is to ensure the GLFMSP's quality system has opportunities to improve the quality of its products. The GLFMSP's quality system uses policies and processes designed to facilitate improvement of the program and data gathering activities. For example, regularly scheduled management meetings, quality system training, data quality assessments, and peer review activities provide opportunities to identify areas for improvement that can be addressed in subsequent projects. Similarly, routine management meetings, quality system assessments, and quality system training are examples of processes that provide opportunities for identifying areas of improvement in the GLFMSP.

6.4.1 Encouraging Staff to Identify and Implement Improvements to Quality

GLFMSP participants are encouraged to seek positive methods for ensuring adherence to GLFMSP's quality system. All participants are expected to use their routine and non-routine staff meetings as a forum for encouraging staff to establish communications between program participants, identify process improvement opportunities, and identify and propose solutions for problems.

6.4.2 Program-level Improvement

This QMP is approved by GLFMSP Manager, GLNPO Quality Manager, and MIRB Chief, thereby demonstrating their commitment to GLFMSP's quality system. GLNPO management is responsible for ensuring that GLNPO staff adhere to the requirements of this quality system as documented in this QMP, and GLFMSP's quality system is constantly being evaluated for effectiveness. This is facilitated through the formal revision, review, and approval process of the QMP every five years.

6.4.3 Project-level Improvement

GLFMSP participants at all levels are accountable for "continuous improvement" of the quality of their products. The process of continuous quality improvement leads to a better and more responsive quality system. The supervisors, project managers, and other technical staff have the most direct experience with the quality system process and are encouraged to identify opportunities for improving the quality system by contacting the GLFMSP Manager directly or through discussion with their management or the GLNPO Quality Manager.

As mentioned above, a variety of tools that are implemented as part of GLFMSP's quality system facilitate improvement. Technical audits, peer reviews, and data quality assessments can improve the quality for the program, subsequent or follow-on projects, and new projects that may be similar in nature. To increase the effectiveness of each data gathering project, the GLFMSP Manager or GLNPO Quality Manager often conduct "debriefing" (or "wrap up") meetings when a project has ended. Such meetings are used as an opportunity to review the QA/QC approaches and documentation used for the project to determine how the plan could have been improved and how similar ongoing projects may benefit from addressing these areas for improvement. The meetings should address all aspects of the data gathering effort, including project planning, field and laboratory procedures, data management, recordkeeping, and the appropriateness of the quality system. Such meetings will assist project planners in identifying "lessons learned" and preventative actions that can be included in future projects.

7.0 Quality Assessments and Response

The GLFMSP conducts quality assessments to ensure that its quality system is effective at producing data of adequate quality to meet program objectives. These assessments are formal evaluations of performance relative to the pre-determined standards outlined in the GLFMSP QMP and QAPPs. Following the evaluation, a response is implemented that provides corrective actions to improve performance where necessary. The GLFMSP uses several tools to conduct its evaluations, including: quality systems audits, technical systems audits, field and laboratory audits or visits, PEs, peer input or program reviews, peer reviews, and data quality assessments. Further information on the application of these tools, including frequency and schedule, is provided in the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8).

7.1 Audits and Site Visits

Quality System Audits and Technical Systems Audits

The GLNPO Quality Manager works together with the GLFMSP Manager to conduct periodic audits of the laboratories performing the chemical analyses. These periodic Quality System Audits (QSAs) are led by the GLNPO Quality Manager and include other members of the Region 5 Quality Team, as well as potential contractors as determined by the GLNPO Quality Manager and GLFMSP Manager. The purpose of QSAs is to determine the compliance of the GLFMSP with its QMP. More information describing these audits can be found in Section 9 of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7). The GLFMSP should conduct a QSA each time a new laboratory takes over the project or once every three years, whichever occurs first.

The GLFMSP is one of GLNPO's high profile monitoring programs, and thus is also subject to periodic TSAs GLNPO QA staff. During these audits, all phases of the program, including sample collection, preparation, and analysis are evaluated qualitatively. TSAs are most beneficial at the start of a project. Because the GLFMSP is a long term monitoring program, GLNPO should perform a TSA whenever a new laboratory or organization becomes substantially involved in the project. More information on TSAs can be found in Section 9 of the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*, (or current) (Appendix A.7).

Field Site Visits

The GLFMSP Manager also conducts periodic site visits to the field collection teams to ensure adherence to the *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities* (Appendix A.8). Because there are many teams out collecting fish at approximately the same time of year, the GLFMSP Manager selects different teams to visit each year, with the goal of visiting each collection team at least once every five years.

The process of conducting QSAs and site visits must be flexible to allow for changes in collection, homogenization, or analytical personnel. For example, certain collection teams may be new or more inexperienced resulting in more frequent audits than teams that have been in place for years and have already demonstrated expertise.

The GLFMSP Manager, along with GLNPO QA staff should plan the audit and document the plan in advance to

ensure an organized and successful audit. The important components of an audit plan are documented in the GLNPO QMP, *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft,* (or current) in section 9.3 (Appendix A.7). This plan must be shared in advance with the party being audited so that they can be prepared with appropriate documents and available personnel during the audit.

The scope and findings of the audit are documented in a report, along with corrective actions that need to be taken. The party being audited is encouraged to review the report and provide comments before the report is deemed final. The final report is sent to GLNPO management. The GLFMSP Manager and GLNPO Quality Manager work with the audited party to follow through on all corrective actions identified in the report. All corrective actions taken are added to final audit report. The GLFMSP Manager and GLNPO Quality Manager determine if any of the corrective actions result in the need to update the GLFMSP QMP or QAPP.

Homogenization Laboratory Quality Assessments

The QA contractor periodically conducts quality assessments of the homogenization laboratory at GLNPO's request. The purpose of these quality assessments is to ensure that the homogenization services that the laboratory is providing for the GLFMSP are in accordance with the SOW and the laboratory's QAPP and SOPs. These quality assessments consist of a detailed review of the laboratory's QAPP and SOPs and an on-site audit. The scope and findings of the quality assessments are documented in a report, along with corrective actions that need to be taken. The homogenization laboratory is encouraged to review the report and provide comments before the report is deemed final. The final report is sent to the GLFMSP Manager and GLNPO Quality Manager. The QA contractor works with the homogenization laboratory to follow through on all corrective actions identified in the report. All corrective actions taken are added to the final report.

7.2 Performance Evaluation

The GLFMSP uses PE samples as another tool to evaluate data quality. PE samples are used when a new laboratory / grantee is awarded the chemical analyses portion of the GLFMSP. Before the grant is awarded, several PE samples are sent to the laboratory for analyses. These samples are of known identity and concentrations to GLNPO, but are blind samples to the analyst. The GLFMSP Manager and GLNPO Quality Manager are then able to evaluate the results to determine whether the Data Quality Objectives (DQOs) and Measurement Quality Objectives (MQOs) have been satisfied. The new laboratory will not be sent GLFMSP samples until they have successfully demonstrated their ability to analyze the PE samples.

Between 2003 and 2006, GLNPO QA personnel conducted a PE study to ensure that Clarkson University was capable of providing data of suitable quality and reproducibility to the program. Clarkson University completed a successful PE analysis before being awarded the GLFMSP. This analysis can be seen in the *Summary of Results for Performance Evaluation Samples Provided to the Potential Grantee Laboratories at Clarkson University, SUNY at Oswego, and SUNY at Fredonia* (Appendix A.6).

Additionally, the GLFMSP participates in a round robin with Environment Canada on a periodic basis. As an example, an evaluation and comparison was conducted on samples from the U.S. and Canada that were collected in 2006 and analyzed in early 2009. In this evaluation, most of the relative percent differences were below 50% which makes comparability acceptable.

When a new laboratory is chosen to provide homogenization services support to the GLFMSP, the laboratory must participate in an initial demonstration of capabilities (IDC) to demonstrate their ability to meet the requirements of the SOW developed by the GLNPO QA contractor. As part of the IDC, the homogenization laboratory carries test samples through the entire sample preparation, homogenization, and aliquoting

procedures separately. Test samples are provided to the analytical laboratory for analysis. The QA contractor evaluates the results of the IDC to determine whether all requirements have been satisfied. The new laboratory will not be sent GLFMSP samples until they have successfully demonstrated their ability to perform homogenization services.

7.3 Peer Input

The GLFMSP utilizes peer input as a tool to assess and enhance the overall quality of the program and to ensure that the program is meeting the needs of its stakeholders. Peer input has been requested of various scientific and technical experts inside and outside the agency over the course of the GLFMSP's existence. Peer input for the GLFMSP has been requested via mail, phone calls, and meetings called program reviews. Program review panels can include scientists directly involved with the GLFMSP and/or the Great Lakes watershed and ecosystem. The goals of these reviews can vary, but they are generally intended to evaluate whether the current program is sufficiently able to meet the needs of its stakeholders. The most recent program review of the GLFMSP was held in the spring of 2005. This program review, *Program Review of the Great Lakes Fish Monitoring Program – Final Report*, can be viewed in Appendix C.9.

7.4 Peer Review

Formal peer reviews play a very important role in the GLFMSP and provide an in-depth assessment of the data that looks at assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions. US EPA has a formal Peer Review Policy that requires reviews to be conducted for all influential scientific information. The GLFMSP is one of GLNPO's most significant monitoring programs and the data are used by US EPA, other government agencies, and environmental groups as an indicator of the health of the Great Lakes. Thus, peer reviews must be conducted periodically to evaluate the program. Peer reviews for GLFMSP are conducted every 5 years; one was conducted in 2007, and the next one is scheduled for 2013.

In a formal peer review, there is an independent third-party review of the program from experts who do not have a material stake in the outcome of the review. One of the main goals of the peer review process is to evaluate the data collected by the program and then determine if the quality of the data is sufficient to meet the objectives of the program. The US EPA Peer Review Handbook can be found at: http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf. Peer reviews result in a written report produced by the review team or by the individual peer reviewers and containing recommendations for potential changes to the program.

7.5 Data Quality Assessments

Data Quality Assessments occur at several different levels in the GLFMSP. As previously described in Section 5.2, each dataset is submitted to a rigorous QA/QC process before it can be entered into the GLENDA database or the GLFMSP Microsoft Access Database. The current QA contractor uses a technical approach developed for GLFMSP data assessments. For more details on this approach, see the *Quality Assurance Project Plan for CSC Support to the Great Lakes Fish Monitoring and Surveillance Program* (CSC, 2011) (Appendix A.2). Data quality audits are an additional tool used to assess the quality of the data being collected. Potential PIs are required to submit sample datasets in the GLENDA reporting format prior to receiving actual sample so that potential data issues can be evaluated and then addressed during the audit.

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Support Documents

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- Extremes of Lake Ontario Lake Trout Migration Patterns By Age
- Great Lakes Fish Advisory Task Force Protocol Drafting Committee. 1993. *Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory*.

List of Appendices – GLFMSP Comprehensive Documentation CD Contents

Appendix A - Current GLFMSP Quality Documentation

A.1. Aquatec Biological Sciences, Inc. 2012. *GLFMSP SOP.*

A.2. CSC. 2011. *Quality Assurance Project Plan for CSC Support to the Great Lakes Fish Monitoring and Surveillance Program.* Version 2.0.

A.3. CSC. 2012. *Report of the Fish Homogenization Services Laboratory Audit of Aquatec Biological Sciences, Inc.*

A.4. Holsen, T. M., P.K. Hopke, B.S. Crimmins, J.J. Pagano, and M.S. Milligan. 2012. *The Great Lakes Fish Monitoring and Surveillance Program: Pushing the Science (GLFMSP).*

A.5. US EPA GLNPO. 2006. *Laboratory Site Visit Report: Clarkson University, State University of New York Oswego, and State University of New York Fredonia, September 25-28, 2006*; Great Lakes National Program Office. Final.

A.6. US EPA GLNPO. 2006. *Summary of Results for Performance Evaluation Samples Provided to the Potential Grantee Laboratories at Clarkson University, SUNY at Oswego, and SUNY at Fredonia*.

A.7. US EPA GLNPO. 2008. *Great Lakes National Program Office Quality Management Plan, Revision 3, Draft*.

A.8. US EPA GLNPO. 2012. *GLFMSP Quality Assurance Project Plan for Sample Collection Activities*. Version 2.0.

Appendix B - Historical GLFMSP Quality Documentation

B.1. CSC. 2005. *Great Lakes Fish Monitoring Program Data Quality Objective Revision Report.*

B.2. CSC. 2008. *Great Lakes Fish Monitoring Program Data Quality Objective Development*.

B.3. FDA. 1983. Pesticide Analysis Method and Personal Note.

B.4. Hesselberg, R.J. 1994. *Analytical Quality Assurance Project Plan: Monitoring Trends of Selected PCB Congeners and Pesticides in Fish from the Great Lakes, 1991, 1992, and 1993.*

B.5. Hesselberg, R.J. 1995. *Analytical Quality Assurance Project Plan - Concentration of PCBs, Trans nonachlor, and Total Mercury in Biota Samples Collected for the Lake Michigan Mass Balance Study*.

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B.9. Swackhamer, D.L. 2004. *Trends in Great Lakes Fish Contaminants.*

B.10. US EPA GLNPO. 2003. *Laboratory Site Visit Report - University of Minnesota, March 6 - 7, 2003*.

B.11. US EPA GLNPO. 2005. *Axys Lab Report of the Fish Sample Homogenization Audit*.

B.12. US EPA GLNPO. 2008. *Great Lakes Fish Monitoring and Surveillance Program Quality Assurance Project Plan for Sample Collection Activities, Revision 0.*

B.13. US EPA GLNPO. 2008. *Great Lakes Fish Monitoring and Surveillance Program Quality Management Plan, Revision 1*.

B.14. Weishaar, J.A. 1983. *FDA Comprehensive Residue Analysis Report for EPA FDA Fish Survey*.

Appendix C - GLFMSP Program Design Documents and Significant Reports

C.1. DeVault, D. 1983. *Fish Consumption Advisories for the Great Lakes*.

C.2. Draft Cooperative Agreement Templates
   a. State Agency
   b. Federal Agency

C.3. Eastern Research Group, Inc. 2008. *Report on the Peer Review Workshop for Great Lakes Fish Monitoring Program – Quality Management Plan and Historical Database.*

C.4. *Eutrophication/Nutrient Monitoring Program – Great Lakes International Surveillance Program 1982*.

C.5. *Great Lakes International Fish Contaminants Surveillance Program Design.*

C.6. IJC. *Contaminants Surveillance Program for the Great Lakes, Rationale and Design*.

C.7. US EPA GLNPO. 1982. *A Great Lakes Perspective, June 1982*.

C.8. US EPA GLNPO. 1996. *Cooperative Agreement Between the U.S. Environmental Protection Agency, Great Lakes National Program Office and the National Biological Service, Great Lakes Science Center on Great Lakes Fish Contaminant Monitoring*.

C.9. US EPA GLNPO. 2005. *Program Review of the Great Lakes Fish Monitoring Program – Final Report*.

C.10. US EPA GLNPO. 2012. *Great Lakes Fish Monitoring and Surveillance Program Data Release Guidelines.*

C.11. US EPA GLNPO. Design Maps:
   a. *Collector locations, atmospheric deposition and acid rain monitoring network*
   b. *Significant Areas of Concern - 1982*
   c. *Open Lake Fish Collection Sites*
   d. *Tributary and Harbor Mouth Collection Sites 1980 – 82*

C.12. US EPA GLNPO/US EPA Region V. 1982. *Fish Monitoring Program Summary*.

C.13. USGS. 2003. *USEPA/GLNPO Cooperative Agreement Withdrawal Memo*.

C.14. Wilford, W.A. 1975. *Contaminants in Upper Great Lakes Fishes*.

C.15. Wilford, W.A. 1982. *Evaluating presence and effects of contaminants in fish in the Great Lakes*.

Appendix D - GLFMSP Significant Events

D.1. Significant Events of the Great Lakes Fish Monitoring and Surveillance Program

Appendix E - GLFMSP Collection Information

E.1. Collection Change Information
   a. Base Monitoring Program notes and analytes
   b. Sport Fish Monitoring Program notes and analytes

E.2. Collection Grid Maps
   a. GLFMSP Historical Sampling Stations Map
   b. GLFMSP Current Sampling Stations Map
   c. Lake Erie Grid Map
   d. Lake Huron Grid Map
   e. Lake Michigan Grid Map
   f. Lake Ontario Grid Map
   g. Lake Superior Grid Map

E.3. Collector Information
   a. Collector Contacts
   b. Collection Grants and IAGs

Appendix F - GLFMSP Publications

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