QUALITY MANAGEMENT PLAN

Prepared for the Environmental Protection Agency
Pursuant to ANSI/ASQC E-4-1994 (*Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*)

We hereby certify that this document discloses the Quality Management Plan (QMP) designed and utilized by the Center for Coastal Resources Management, Virginia Institute of Marine Science of the College of William & Mary. The policies and procedures described herein detail the core of our documented administrative management process and are regularly reviewed, updated and transmitted to Center personnel.

This Management QMP represents our commitment to ensure that all Center activities are managed in accordance with appropriate regulation and guidelines.

Signed:

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Carl Hershner, Director

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Kirk Havens, Asst. Director & Quality Assurance Manager

Center for Coastal Resources Management, Virginia Institute of Marine Science, College of William & Mary

Quality Management Plan

INTRODUCTION

This document has been prepared pursuant to requirements from the Environmental Protection Agency (EPA) to provide an overview and description of Quality Management of EPA projects at the Center for Coastal Resources Management (CCRM), Virginia Institute of Marine Science (VIMS) and is submitted as a Center for Coastal Resources Management Quality Management Plan (CCRM QMP). The oversight provide by the CCRM QMP is in addition to the Quality Assurance Project Plans (QAPP) prepared for each individual research project supported by EPA.

Based on guidance in EPA QA/R-2, the CCRM QMP is organized, to the extent possible, following the Section headings in Chapter 3 of EPA QA/R-2. Further, QA/R-2 notes that widely differing organizations and programs are supported by EPA funding and not every recommended managerial control is appropriate for every entity. As a Center within the College of William & Mary with a wide-ranging and diverse research portfolio coupled with extensive College of William & Mary research compliance requirements, CCRM is able to provide a "structured process" together with a "tiered approach" for quality management.

The Center for Coastal Resources Management conducts applied research and serves as a scientific advisor to federal, state and local agencies, and the general public. The Center recognizes the importance of how work processes are implemented to ensure that data collected are of the needed and expected quality for their desired use. In order to provide accurate information to user groups, the CCRM is dedicated to an aggressive, proactive Quality Assurance and Quality Control program.

A myriad of activities occur within the Center, including direct support of laboratory and field investigations, support and training of graduate students and interns, training of resource agency personnel and the public, direct support of state agencies and local governments, and sponsorship of lectures, seminars, conferences and visiting scientists. Research activities include both field and laboratory measurements and the development and validation of ecological models. The general goal of the CCRM Quality System is to ensure accurate, reproducible, and unbiased data.

CCRM faculty and staff researchers are committed to quality in conducting research and compiling data and maintain the highest standards in data management and archiving. Additionally, EPA projects are supported by QAPPs prepared specifically for individual scopes of work, and each project has a designated Principal Investigator with a staff trained specifically for the particular scope of work. This is in addition to Center-wide training required of all staff members engaged in Center research.

In order to limit the length of this QMP while providing access to in-depth information and full documentation, internet addresses and links rather than extensive quotations are included whenever possible.

Presently, CCRM routinely conducts projects that build the capacity of state/tribal/local governments to increase the quantity and quality of wetlands in the United States. These activities are conducted by CCRM personnel in accordance with individualized EPA-approved QAPPs.

MISSION AND QUALITY POLICY OF THE CENTER

The CCRM is a Center within the Virginia Institute of Marine Science of the College of William & Mary which is a public university in the Commonwealth of Virginia. The Virginia Institute of Marine Science serves as the graduate School of Marine Science for the College of William & Mary and for more than 70 years has been charged by the Commonwealth to serve as the state's entity for research and advisory support on issues affecting Virginia's natural resources. The CCRM/VIMS is particularly charged with providing advice on the Commonwealth's wetlands resource as described as **DUTIES AND MISSION** in Virginia Code:

§ 28.2-1100. Virginia Institute of Marine Science continued; duties.
The Virginia Institute of Marine Science shall hereafter be referred to as the Institute. The Institute shall:
5. Conduct hydrographic and biological studies of the Chesapeake Bay, its tributaries, and all the tidal waters of the Commonwealth and the contiguous waters of the Atlantic Ocean;
6. Engage in research in the marine sciences;
7. Conduct such special studies and investigations concerning these subjects as requested by the Governor; and
8. Engage in research and provide training, technical assistance and advice to the Board on Conservation and Development of Public Beaches on erosion along tidal shorelines, the Soil and Water Conservation Board on matters relating to tidal shoreline erosion, and to other agencies upon request.
9. Develop comprehensive coastal resource management guidance for local governments to foster the sustainability of shoreline resources by December 30, 2012. The guidance shall identify preferred options for shoreline management and taking into consideration the resource condition, priority planning, and forecasting of the condition of the Commonwealth's shoreline with respect to projected sea-level rise.
These studies shall include consideration of the seafood and other marine resources, such as the water, bottoms, shore lines, tidal wetlands, and beaches, and all matters related to marine waters and the means by which marine resources might be conserved, developed and replenished (Code 1950, §§ 28-248, 28-250, 28-250.1; 1962, c. 406, § 28.1-195; 1979, c. 294; 1980, c. 369; 1992, c. 836).
Further, pursuant to Virginia Code § 28.2-1101. Use of services of other agencies; solicitation, etc., of funds; taking fish and other marine organisms.

1. *Use of services of any public or private agency;*
2. *With the prior written approval of the Governor and subject to other provisions of law, solicit, accept and use funds available from any public or private source; and*

Cooperate with appropriate state agencies and with similar agencies and institutions in other state and the federal government.

§ 15.2-2223.3. Comprehensive plan shall incorporate strategies to combat projected sea-level rise and recurrent flooding.
Beginning July 1, 2015, any locality included in the Hampton Roads Planning District Commission shall incorporate into the next scheduled and all subsequent reviews of its comprehensive plan strategies to combat projected relative sea-level rise and recurrent flooding. Such review shall be coordinated with the other localities in the Hampton Roads Planning District Commission. The Department of Conservation and Recreation, the Department of Emergency Management, the Marine Resources Commission, Old Dominion University, and the Virginia Institute of Marine Science shall provide technical assistance to any such locality upon request. Where federal regulations as effective July 1, 2015 require a local hazard mitigation plan for participation in the Federal Emergency Management Agency (FEMA) National Flood Insurance Program, such a plan may also be incorporated into the comprehensive plan. For a locality not participating in the FEMA Community Rating System, the comprehensive plan may include an action plan and time frame for such participation.
2015, c. 186.

§ 28.2-1301. Powers and duties of the Commission.
A. The Commission may receive gifts, grants, bequests, and devises of wetlands and money which shall be held for the uses prescribed by the donor, grantor, or testator and in accordance with the provisions of this chapter. The Commission shall manage any wetlands it receives so as to maximize their ecological value as provided in Article 2 (§ 28.2-1503 et seq.) of Chapter 15 of this title.
B. The Commission shall preserve and prevent the despoliation and destruction of wetlands while accommodating necessary economic development in a manner consistent with wetlands preservation.
C. In order to perform its duties under this section and to assist counties, cities, and towns in regulating wetlands, the Commission shall promulgate and periodically update guidelines which scientifically evaluate vegetated and nonvegetated wetlands by type and describe the consequences of use of these wetlands types. The Virginia Institute of Marine Science shall provide advice and assistance to the Commission in developing these guidelines by evaluating wetlands by type and continuously maintaining and updating an inventory of vegetated wetlands.

§ 28.2-104.1. Living shorelines; development of general permit; guidance.
A. As used in this section, unless the context requires a different meaning:
"Living shoreline" means a shoreline management practice that provides erosion control and water quality benefits; protects, restores or enhances natural shoreline habitat; and maintains coastal processes through the strategic placement of plants, stone, sand fill, and other structural and organic materials.
B. The Commission, in cooperation with the Department of Conservation and Recreation, the Department of Environmental Quality, and local wetlands boards, and with technical assistance from the Virginia Institute of Marine Science, shall establish and implement a general permit regulation that authorizes and encourages the use of living shorelines as the preferred alternative for stabilizing tidal shorelines in the Commonwealth. The regulation shall provide for an expedited permit review process for qualifying living shoreline projects requiring authorization under Chapters 12 (§ 28.2-1200 et seq.), 13 (§ 28.2-1300 et seq.), and 14 (§ 28.2-1400 et seq.). In developing the general permit, the Commission shall consult with the U.S. Army Corps of Engineers to ensure the minimization of conflicts with federal law and regulation.
C. The Commission, in cooperation with the Department of Conservation and Recreation and with technical assistance from the Virginia Institute of Marine Science, shall develop integrated guidance for the management of tidal shoreline systems to provide a technical basis for the coordination of permit decisions required by any regulatory entity exercising authority over a shoreline management project. The guidance shall:
1. Communicate to stakeholders and regulatory authorities that it is the policy of the Commonwealth to support living shorelines as the preferred alternative for stabilizing tidal shorelines;
2. Identify preferred shoreline management approaches for the shoreline types found in the Commonwealth;
3. Explain the risks and benefits of protection provided by various shoreline system elements associated with each management option; and
4. Recommend procedures to achieve efficiency and effectiveness by the various regulatory entities exercising authority over a shoreline management project.
2011, c. 885; 2014, cc. 112, 143.

§ 62.1-44.2. Short title; purpose.
The short title of this chapter is the State Water Control Law. It is the policy of the Commonwealth of Virginia and the purpose of this law to: (1) protect existing high quality state waters and restore all other state waters to such condition of quality that any such waters will permit all reasonable public uses and will support the propagation and growth of all aquatic life, including game fish, which might reasonably be expected to inhabit them; (2) safeguard the clean waters of the Commonwealth from pollution; (3) prevent any increase in pollution; (4) reduce existing pollution; (5) promote and encourage the reclamation and reuse of wastewater in a manner protective of the environment and public health; and (6) promote water resource conservation, management and distribution, and encourage water consumption reduction in order to provide for the health, safety, and welfare of the present and future citizens of the Commonwealth.
Code 1950, § 62.1-14; 1968, c. 659; 1970, c. 638; 1978, c. 827; 2000, c. 972.
(16) To establish and implement policies and programs to protect and enhance the Commonwealth's wetland resources. Regulatory programs shall be designed to achieve no net loss of existing wetland acreage and functions. Voluntary and incentive-based programs shall be developed to achieve a net resource gain in acreage and functions of wetlands. The Board shall seek and obtain advice and guidance from the Virginia Institute of Marine Science in implementing these policies and programs.

QUALITY POLICY: The CCRM is a Center within the Virginia Institute of Marine Science (VIMS). VIMS is the School of Marine Science within the College of William & Mary. The College of William & Mary's mission statement is an integral part of CCRM quality policy which is articulated in Chapter III. F. (Allegations of Violations of Policy) of the College of William & Mary Faculty Handbook, http://www.wm.edu/about/administration/provost/documents/facultyhandbook.pdf. Extracted below is the statement of policy regarding misconduct in scholarly and research activity (pp. 56-57). The handbook specifically addresses inquiries, reporting requirements, investigations, and consequences.

Academic Misconduct in Scholarly Activity or Research.

It is the responsibility of faculty and administrators at the College to create and sustain an atmosphere where honesty and integrity are paramount in the conduct and dissemination of research and scholarly and creative activity; this responsibility extends to documentation prepared for the purpose of securing assistance in the pursuit of scholarly activity or research. It is the particular responsibility of individual scholars and researchers to ensure that the quality of published works is maintained: products must be carefully reviewed prior to publication; the accomplishments of others must be recognized and cited; contributors must be given full acknowledgement; co-authorship must be conferred to those, and only those, who have made a significant contribution; and all (co-)authors must be willing and able to defend publicly their contribution to the published results. It is also the responsibility of the College administration and faculty to make undergraduate and graduate students aware 1) of the College policies governing the conduct of scholarly activities and research, and 2) that students as well as faculty members are held to these policies while conducting research.

a. ***Definitions of Academic Misconduct.*** *Although it may be more specifically defined by the discipline and/or in the school or department, academic misconduct is broadly defined to include fraudulent behavior such as "fabrication, falsification, plagiarism, [misappropriation,] or other*

b. *practices that seriously deviate from those that are commonly accepted within [the particular scholarly community] for proposing, conducting, or reporting research [or other scholarly endeavors]. It does not include honest error or honest differences in interpretations or judgments" of results of scholarly activity.*

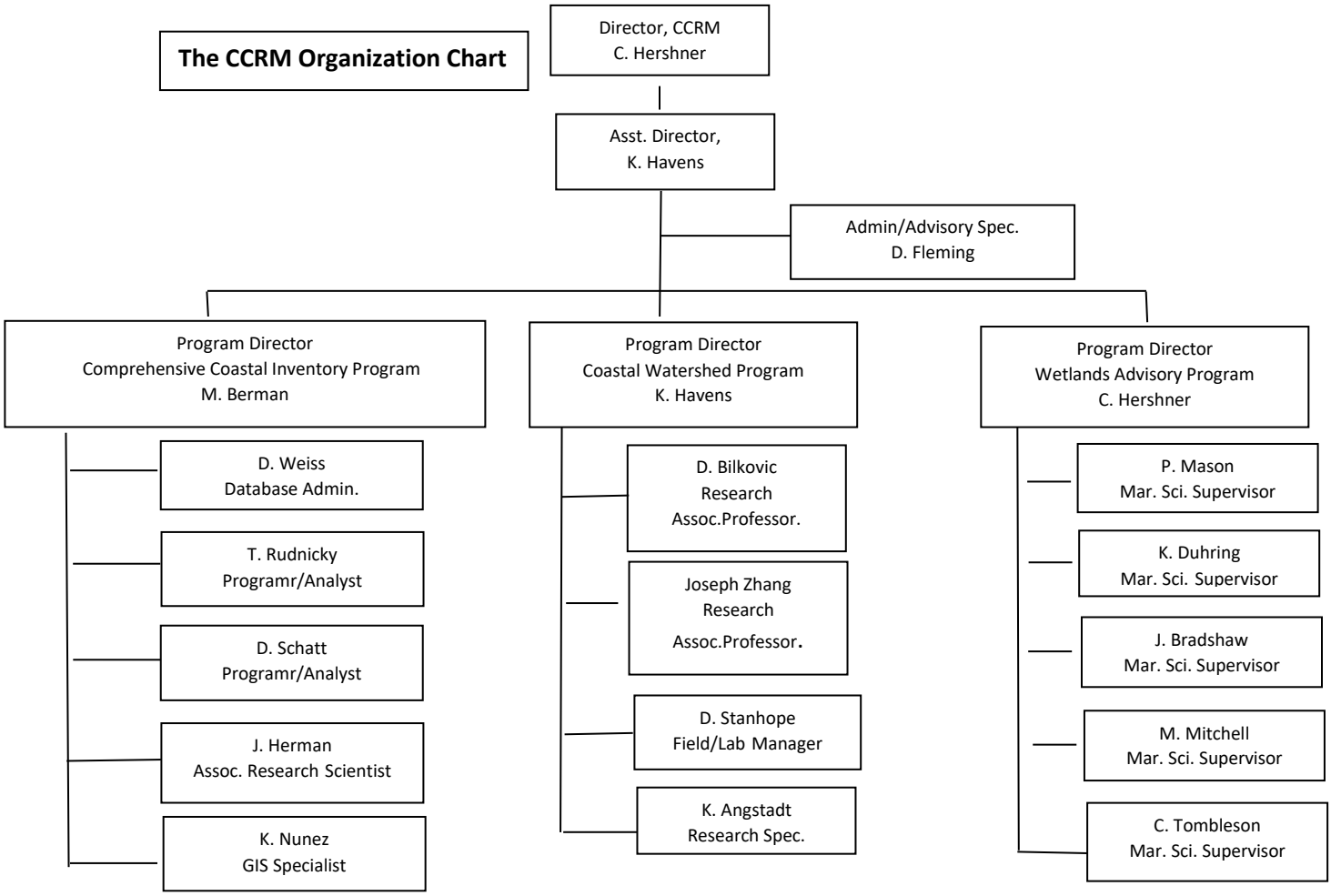
- *Falsification ranges from fabrication to deceptively selective reporting and includes the purposeful omission of conflicting data with the intent to condition or falsify results.*

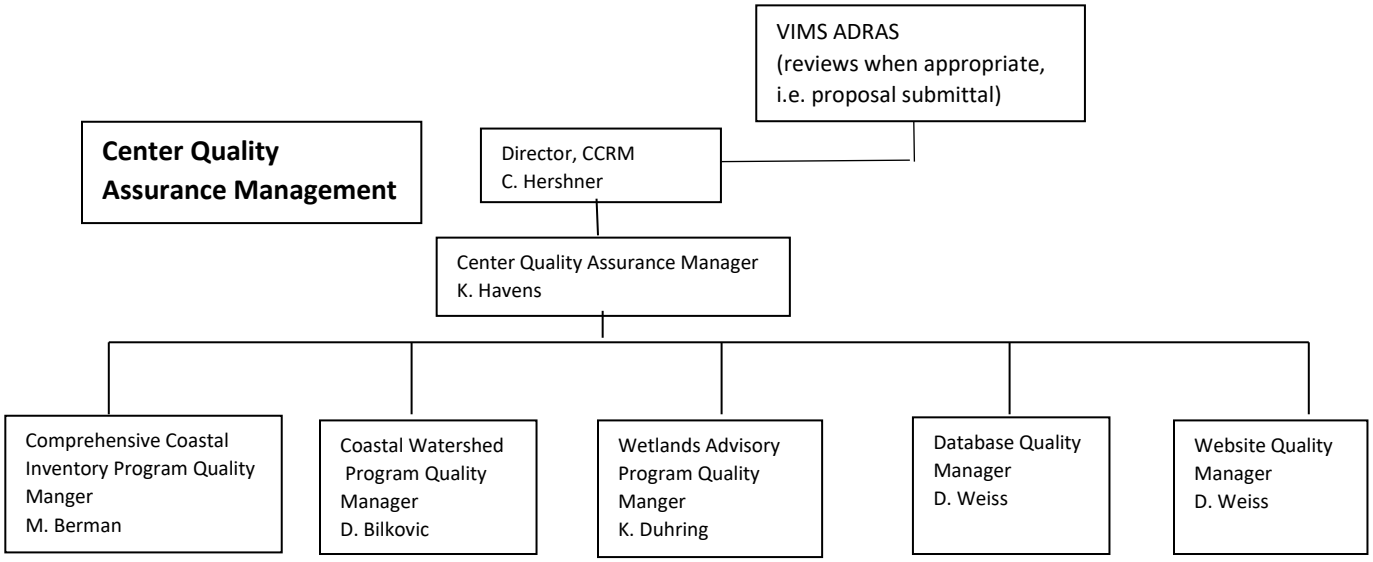
- *Plagiarism and misappropriation involve willfully appropriating the ideas, methods, or written words of another, without acknowledgement and with the intention that they be taken as one's own work, as well as the unauthorized use of privileged information (such as information gained confidentially in peer review).*

Academic misconduct also includes material failure to comply with legal requirements governing research, including requirements for the protection of researchers, human subjects, or the public, or for ensuring the welfare of laboratory animals.

Additional information is provided on the College of William & Mary's Research Compliance webpage http://www.wm.edu/offices/sponsoredprograms/researchcompliance/research%20integrity%20and%20conflicts%20of%20interest/index.php including the Collaborative Institutional Training Initiative (CITI) online training modules http://www.wm.edu/offices/sponsoredprograms/researchcompliance/onlinetraining/index.php.

MANAGEMENT AND ORGANIZATION





QUALITY SYSTEM COMPONENTS

The Center recognizes the need for specific plans for individual data collection operations to ensure that data or information collected are of the needed and expected quality for their desired use. As a Center, the quality assurance operation procedures differ from that of an individual research contract. Each principal investigator is responsible for submitting a project-specific quality assurance plan to the relevant EPA Program Quality Assurance Manager and the Center Quality Assurance Manager. The principal investigators will use the underlying principles described in this document as a framework for the specific quality assurance and quality control plans for each project. These plans should detail:

- The specific objectives of the project, including the hypothesis to be tested.
- The data quality objective for the variables to be measured.
- The specific sampling and analytical protocols required to meet the data quality objective.
- The individual responsible for quality assurance for the project.
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All noncompliance or deviation from the approved quality assurance plan will be reported to the Program Quality Assurance Manager and the Center Quality Assurance Manager.

STANDARD OPERATING PROCEDURES: CCRM maintains Standard Operating Procedures (SOPs) that accurately reflect all laboratory and field activities. These SOPs provide detailed information to personnel on the performance of their work. Copies of all SOPs are accessible to personnel and are located within each Program and on the Center website.

SOPs are used to ensure consistency and efficiency. Field sampling and laboratory analytical methodologies employed in each Center project will be internally consistent and compatible with previous projects. Any deviation from an established procedure is documented.

The Program Quality Manager is responsible for ensuring that work is performed according to the approved Program SOPs as well as identification of operations needing procedures, preparation, review, approval, revision, and withdrawal of these procedures and policy for use. The Program Quality Manager is responsible for controlling and documenting the release, change, and use of planned procedures, including any necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that changes are made as prescribed. SOPs are maintained for the following programs within the Center:

A. Coastal Watershed Program
B. Comprehensive Coastal Inventory Program
C. Wetlands Advisory Program

All SOPs are reviewed yearly by the Center Quality Manager and the Program Quality Managers and are developed according to the following documents:

- American National Standard. 1995. Specifications and guidelines for quality systems for environmental data collection and environmental technology programs. American Society for Quality Control, Energy and Environmental Quality Division, Environmental Issues Group, Milwaukee, Wisconsin.

- EPA QA/G-6. 1995. Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality Related Documents.

- Taylor, J.K. 1985. The quest for quality assurance. American Laboratory 17:67-75.

PROPOSAL SUBMISSION: All CCRM proposals are reviewed prior to submission to ensure compliance with the Institutional Animal Care and Use Committee (IAUCC), the Institutional Biosafety Committee (IBC), and the Protection of Human Subjects Committee (PHSC).

These additional reviews during the proposal submission process and throughout the project support the CCRM QMP by:

1. Fulfilling federal legal requirements;
2. Providing an additional level of research oversight by scientists not directly involved in the work being proposed or conducted.

Proposal submissions are not complete until the investigator has submitted an on-line Routing and Review Form at: https://www3.vims.edu/sprograms/sp_tracker/ROUTE_REVIEW/route_review.cfm which is restricted to avoid unauthorized access. Completion of the digital routing/review form and submission of protocols, as required, to the appropriate oversight committee(s) provides an additional layer of audit/evaluation for research activities. Proposal Submission Requirements are listed here http://www.vims.edu/about/leadership/sponsored_programs/apply/index.php and appropriate links to the webpage "EPA Quality System" are included on the Office of Sponsored Programs webpage at

AWARD CONFIRMATION: If a proposal is recommended for funding, investigators are required to give a copy of an approved QAPP for the Office of Sponsored Programs before work begins and before any expenditures are authorized.

The formal institutional notification form for an EPA Region III award contains a statement that the project must have and maintain an approved QAPP.

The CCRM Director and CCRM Quality Assurance Manager receive a copy of Notification Forms. It is the responsibility of the CCRM Quality Assurance Manager to coordinate with the researchers, periodically reviewing reports and data files as appropriate as an integral part of the CCRM Quality Management Plan.

PERSONNEL QUALIFICATIONS AND TRAINING

HIRING: CCRM QMP for hiring and personnel procedures are established under state policies as articulated by the Commonwealth's Department of Human Resources Management. The website for that agency is located at: http://www.dhrm.virginia.gov/. The College of William & Mary website describes state and institutional policies and provides electronic copies of mandatory personnel forms http://www.wm.edu/HR/index.php.

In addition, the College of William & Mary has a site available providing information about job openings and employment regulations as well as copies of employee and faculty policies and issues http://www.wm.edu/offices/hr/careers/index.php. All positions are competitive. Job postings are advertised and interviews conducted to ensure identification and selection of the best qualified applicants for open positions. Candidates must meet educational and experience requirements for the positions advertised, and all individuals selected must undergo a background check. Each employee has an annual performance evaluation.

TRAINING: The Center is committed to providing quality training to ensure that all staff have the necessary skills to effectively accomplish their work. This may include training with specific instruments and equipment, software, sampling protocols, or continuing education. The Program Director in consultation with the Center Quality Assurance Manager ensures that all personnel within the respective programs have the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, accreditations, licenses, or other formal qualifications necessary for the performance of their tasks. Program Quality Managers are responsible for identifying retraining needs. The Center encourages continuing undergraduate and graduate level courses at the Virginia Institute of Marine Science, the College of William & Mary, and other accredited Universities for staff to increase their knowledge and skills.

SAFETY: Supervisors must ensure that all new or reassigned personnel are instructed in safe methods of performing particular tasks prior to starting or during the early stages of each new job. A general safety briefing is held in conjunction with the Hazard Communication Standard training for every new employee. Additional information regarding safety protocols is located here http://www.vims.edu/about/leadership/operations/index.php.

RESEARCH COMPLIANCE: Training modules must be completed by any faculty or staff member working with animal subjects and while most of the CCRM work involves wetlands plants, hydrology, soils, and modeling there are occasions when sampling of the fauna is necessary. The modules are online and available at the WM Self-Service website http://my.wm.edu. These are password protected and not open to the general public. Each Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC) protocol is approved for three years; an annual renewal request is also needed to stay current and allow the IACUC to confirm that research protocols are being followed. Protection of Human Subjects Committee (PHSC) protocols are submitted and reviewed annually. Any significant changes taking place during the year must be reported to the appropriate committee for additional review. In the event a researcher does not have an approved protocol for a research project, work may not begin until an approved protocol is in place.

A statement of compliance requirement is distributed twice annually to all investigators as a reminder that research data must be collected in a manner consistent with federal mandates.

The memo states (in part):

Research is an integral part of academic life that is highly regulated by state and federal laws which must be obeyed. We have an obligation to perform research using the best available safety practices. ***Please share this message with visitors, students, post docs, and others in your area, all of whom might perform research that could fall into one of the regulated areas discussed below.***

Federal Regulations require formal review for certain classes of activity ***BEFORE*** *employees* ***or*** *students begin work. Review is required whether these regulated activities are supported by external or internal funds, whether they are performed as research or as part of normal instruction in a classroom, lab, or practicum, whether they are performed on or off College grounds, and whether they are part of a formal research program or undertaken as the result of academic curiosity on the part of a professor or student.*

Regulated areas of concern include:

PHSC *- Work that involves living human subjects* ***including*** *survey research or questionnaires;*

IACUC *- Work that involves the use and care of vertebrate animals;*

RAD *- Work that uses or produces radioactive materials; and*

IBC *- Work that involves institutional bio - safety concerns such as:*

- *Recombinant DNA*
- *Work with any human fluid, tissue or infectious agent*
- *Research involving direct or indirect contact with wild - caught animals that may harbor infectious agents*

Investigators must submit compliance proposals that include detailed step-by-step procedures to be used in the research prior to the commencement of work.

Further, compliance committee review is required for survey work that may be done year-after-year in scheduled classes or laboratories. ***Annual renewals are not automatic****. Researchers must update protocols annually in order to continue the work. Any modification in the authorized protocol during the period covered by VIMS Safety and Environmental Programs at the protocol must undergo additional review* ***prio****r to implementation.*

A detailed description of the compliance committees, along with guidance for investigators, is available on the College's Research Compliance website:

http://www.wm.edu/offices/sponsoredprograms/researchcompliance/guidanceandprocedures/index.php

Individuals who will perform, or intend to perform, a particular activity involving regulated areas may ***not*** *judge for themselves whether that work is exempt from formal review. If you have questions you should either submit your proposed activity through the Protocol and Compliance Management electronic submission program for review or contact a Committee Chair to discuss it. Written committee approvals must be in place prior to beginning any project.*

An increasingly important compliance responsibility is creating and maintaining oversight and training about the role of ethical conduct in research and management of potential conflicts of interest. Several federal agencies mandate training in the Responsible Conduct of Research (RCR) prior to processing proposals or making awards:

http://www.wm.edu/offices/sponsoredprograms/researchcompliance/research%20integrity%20and%20conflicts%20of%20interest/nsfmisconduct/index.php

William & Mary must annually renew its assurance with the Public Health Service's Office of Research Integrity and confirm that we have a formal policy. Further, the report must include details of any misconduct allegations, inquiries and investigations handled in the previous year. We encourage you to review the guidance found in the Faculty Handbook:

http://www.wm.edu/about/administration/provost/forfacstaff/faculty-handbook/index.php

It is the faculty member's responsibility to ensure that any potentially hazardous procedures will be specifically identified in protocols submitted to the College compliance committees (e.g., IBC, Radiation Safety, IACUC, and Human Subjects). If the research activity does not require formal compliance review, the faculty member should ensure that general laboratory and field safety protocols are documented, relevant, and enforced.

Federal law also governs the use and management of Select Agents. At W&M oversight of Select Agents falls under the purview of the Environmental Health and Safety Office. A complete list of Select Agents and Toxins may be found at http://www.selectagents.gov/SelectAgentsandToxinsList.html

Questions about Select Agents should be directed to Sandra Prior, Director of EHS at slprio@wm.edu.

VIMS faculty/staff should address questions to Tom Grose, Director at twgrose@vims.edu.

The College of William & Mary Intellectual Property Policy, which applies to all students, employees, and visitors of W&M, has recently been amended. The amended policy can be found here: http://www.wm.edu/offices/techtransfer/policies/index.php . If you have any questions about the policy, please contact the Technology Transfer Office http://www.wm.edu/offices/techtransfer/index.php).

It is the college's policy to comply with all United States Export Control laws and regulations that apply to certain activities involving corporations or citizens of certain foreign countries. Export Control issues are assessed on a case by case basis. Additional information may be found on the Technology Transfer Office website: http://www.wm.edu/offices/techtransfer/ExportControls/index.php

Faculty, staff and students should be aware of basic compliance and safety requirements. The College has available a series of training modules covering a variety of topics including responsible conduct of research, animal care, biosafety, human subject research, and export controls. The modules can be accessed at https://www.citiprogram.org. We encourage everyone to take advantage of the training opportunities.

PROGRAM SPECIFIC TRAINING: Project investigators are responsible for ensuring that staff members receive training on new software, data management, and other research protocols as appropriate to the specific program. Funding is made available for attendance at classes, seminars, and conferences and training plans and protocols may be included in the individual QAPP submitted for each project.

CONFLICT OF INTEREST AND ECONOMIC DISCLOSURE: The College of William & Mary, as well as the Commonwealth of Virginia, requires employees subject to the State and Local Government Conflict of Interest Act, to complete Conflict of Interest Act training every two years in addition to completing the annual Statement of Economic Interest. This training is provided by the Virginia Conflict of Interest and Ethics Advisory Council at http://ethics.dls.virginia.gov/

The Virginia Conflict of Interest and Ethics Advisory Council was created by the Virginia General Assembly to encourage and facilitate compliance with the State and Local Government Conflict of Interests Act (§ 2.2-3100 et seq.), the General Assembly Conflict of Interests Act (§ 30-100 et seq.) and the lobbying laws in Article 3 (§ 2.2-418 et seq.)

Assurance that there is no financial or academic conflict regarding a faculty member's research is the portion of the QMP that supports 40 CFR § 30.42, EPA's codification of OMB A-110 "Code of Conduct" clause.

PROCUREMENT OF ITEMS AND SERVICES:

To secure goods and services competitively and externally from the College of William & Mary, procurement procedures must be conducted in a fair and impartial manner and fully conform to state law and the Commonwealth of Virginia Purchasing Manual for Institutions of Higher Education and their Vendors. The Virginia Public Procurement Act (VPPA, DGS/DPS, July 2017) mandates that competition in procurement is utilized to the maximum feasible extent https://dgs.virginia.gov/procurement/policy-consulting--review/policy/.

The College e-procurement system is eVA. The SPCC (Small Purchase Charge Card) program is required for all purchases under $5000.00 (unless the company sends documentation that they do not accept credit cards) https://eva.virginia.gov/cd/files/evafact3buy-suptools.pdf.

The College of William & Mary is one of nine publicly-funded Commonwealth of Virginia colleges and universities that are specifically designated as members of the Virginia Association of State Colleges and University Purchasing Professionals (VASCUPP). Additional information can be obtained in the VASCUPP Purchasing Manual for Institutions of Higher Education and their Vendors. This manual is a comprehensive reference source specific to the purchasing departments of fully decentralized institutions of higher education under the Commonwealth's pilot decentralization program (http://vascupp.org/hem.pdf).

Online reference and access to additional procurement information is provided on the VIMS website at http://www.vims.edu/admin/accounting.html

Internal services for analytical processes are handled by the VIMS Analytical Service Center. The Analytical Service Center researches, develops, and refines methodologies for analyses in a wide spectrum of environmental matrices. ASC instrumentation is of the current generation: computer control/acquisition, background correction, and all optimized for saline matrix. Extensive field

experience has created a suite of well-honed sampling and processing procedures, and specialized equipment. Copies of all ASC SOPs are on file in the VIMS library.

DOCUMENTS AND RECORDS

Data retention and record management is the responsibility of each individual investigator in collaboration with the EPA program manager and must be planned, documented and submitted with the QAPP for each project.

DATA REDUCTION AND INITIAL REVIEW: Data are reviewed and validated to ensure that the data are properly reduced and properly transcribed to the correct reporting format. Raw data from field and laboratory samples are reduced according to Program SOPs. Computer programs used for data reduction are validated before use and verified by manual calculations on a regular basis. All information used in sample preparation, field data collection, and calculations is recorded and maintained in order to enable reconstruction of the final result at a later date. Staff reports any noncompliance to the supervisor and initiate corrective action. The principal investigator reviews all data, records, and associated documents.

SECONDARY DATA REVIEW: All data are reviewed by a second researcher or supervisor according to field and laboratory procedures to ensure that calculations are correct and to detect transcription errors. Spot checks are performed on computer calculations to verify program validity. Errors detected in the review process are referred to the principal investigator for corrective action. After the secondary review, the second researcher or supervisor signs each page of raw data.

METADATA: Metadata is “data about data” and describes the content, quality, condition and other characteristics of data. Metadata is provided for all Center datasets. The three main functions of metadata are to:

- Preserve the meaning and value of a data set.
- Contribute to a catalog or clearinghouse.
- Aid in data transfer.

RECORDS: The Center recognizes the need to maintain quality-related documents and records. Records provide the direct evidence and support for the necessary technical interpretations, judgments, and discussions concerning Center results. These records provide the historical evidence needed for later reviews and analyses. All records are retained for a minimum of 5 years.

The Principal Investigator, Program Director, Database Quality Manager and Program Quality Manager identify quality-related documents and ensure that the records and documents accurately reflect completed work and are responsible for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition.

Field and laboratory records generally consist of electronic tablets, notebooks, equipment maintenance and calibration forms, chain-of-custody forms, and personnel qualification and training forms. Records that are stored or generated by computers have hard copies or write-protected backup copies.

LONG TERM DATA STORAGE: The long-term data storage plan includes the deposition and preservation of all data and metadata. The CCRM uses the College's William & Mary (W&M) Publish online repository. W&M Publish is an open-access repository and online publishing platform for W&M's academic, and creative communities. Its purpose is to provide wide and stable access to the work of W&M faculty, researchers, students, and staff. W&M Publish hosts notable scholarly and creative content that is produced, submitted, or sponsored by W&M faculty, researchers, or staff.

Content hosted by W&M Publish is widely searchable and accessible, enhancing the visibility and reach of William & Mary's intellectual output within the global community. The W&M Libraries administer W&M Publish https://publish.wm.edu/about.html

Center records include the following:

- *Standard Operating Procedures.* Any revisions to field and laboratory procedures are written, dated, and distributed to all affected individuals to ensure implementation of changes.
- *Equipment Maintenance Documentation.* A history of the maintenance record of each system serves as an indication of the adequacy of maintenance schedules and parts inventory. As appropriate, the maintenance guidelines of the equipment manufacturer are followed. When maintenance is necessary, it is documented in logbooks.
- *Calibration Records.* The frequency, conditions, standards, and records reflecting the calibration history of a measurement system are recorded.
- *Original Data.* Field and laboratory raw data and calculated results are maintained in notebooks, logs, files, or other tracking or data entry forms.
- *Metadata.* Explanatory information about all created databases is stored on the Center computer files.
- *Correspondence.* Correspondence pertinent to a project is scanned and stored in the Center computer files.
- *Deviations.* All deviations from SOPs are reviewed and approved by the Program Quality Manager.
- *Administrative Records.* Personnel qualifications, experience and training records are stored in the Center computer files.
- *Final Reports.* At the end of the project period, each principal investigator certifies submission of a final report and/or all other data and/deliverables to the funding agency, in a format consistent with agency requirements. Confirmation of submission and agency acceptance of reports must occur prior to CCRM and VIMS project closeout.

In addition to datasets, copies of final reports are preserved within William & Mary Publish.

As appropriate and possible, investigators are expected to submit publications derived from project activities to professional journals and at conferences and meetings for peer review of research activities and conclusions.

COMPUTER HARDWARD AND SOFTWARE

Hardware and software needs for each project are identified in individual QAPPs. As noted above, staff members are hired and trained to ensure that programs are staffed to fulfill the goals of data collection

and management of the project. The Center recognizes the importance of computer hardware and software QA/QC protocols to record and maintain data. In addition, VIMS has an Information Technology and Networking Services (ITNS) that serves the CCRM and VIMS in selection, purchase, and maintenance of technology resources.

The CCRM Database Quality Manager in consultation with the Center Quality Manager, the Program Director, the Program Quality Manager, and the Principal Investigator (when appropriate) is responsible for developing, installing, testing, maintaining, controlling, and documenting computer hardware and software used in data collection and storage. The Database Quality Manager, in consultation with VIMS ITNS, is responsible for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance. The Database Quality Manager, in consultation with the Principal Investigator, is responsible for evaluating purchased hardware and software to ensure it meets project requirements and complies with applicable contractual requirements and standards. The Principal Investigator, in consultation with the Database Quality Manager is responsible for ensuring that the data and information produced from, or collected by, computers meet applicable information source management requirements and standards.

VIMS ITNS Mission

To facilitate the missions of VIMS (education, research and advisory services) and to enhance the productivity of the VIMS community (faculty, staff and students).

- Explore the information technology resource requirements of the VIMS community
- Plan and develop a flexible and scalable information technology infrastructure that can deliver those resources to the VIMS community
- Identify and promote a set of cost effective and supportable information technology services that can be reliably delivered to the VIMS community
- Develop and seek support for policies that will assure security, stability and supportability of IT resources for the VIMS community

ITNS is responsible for the overall stability and management of the VIMS network. Devices (i.e. servers, computers, printers, and network equipment) that are attached to the network must be configured correctly to ensure the stability and security of the network. ITNS assists the VIMS community in the selection and implementation of equipment and software that will function in the VIMS network environment. ITNS assists the VIMS community by fixing problems that occur within the VIMS network environment in a timely manner. ITNS recommends the acquisition of equipment and software that will perform well and minimize the on-going support costs. Additional information on ITNS User Guides (including IT Security, Account Access, Telephone Access & Usage, Computer Access & Usage), Policies, & Procedures can be found here http://www.vims.edu/intranet/itns/mission/index.php.

PLANNING

Data operations for each project supported by EPA are defined and described in the specific proposal and QAPP submitted by the investigator. The QAPP is reviewed and approved at the Center and

Institutional level by the CCRM Quality Manager and the VIMS Associate Dean of Research and Advisory Services.

IMPLEMENTATION OF WORK PROCESSES

If a proposal is recommended for funding, investigators are required to provide an approved QAPP to the Office of Sponsored Programs before work begins and expenditures are authorized. The formal institutional notification form for an EPA award contains a statement that the project must have an approved QAPP and that the CCRM Quality Manager and the VIMS Associate Dean of Research and Advisory Services (ADRAS) must review each project annually for data management compliance with the approved plan. The CCRM Quality Manager and the VIMS ADRAS receive copies of notification forms. It is the responsibility of the CCRM Quality Manager and the VIMS ADRAS to coordinate with the researchers and review their reports and data files at least annually as an integral part of the CCRM and VIMS Quality Management Plans.

ASSESSMENT AND RESPONSE

Environmental audits are performed for Region III Environmental Protection Agency awards by EPA staff members who come to CCRM and review data collected and managed by the Principal Investigators. Copies of any audits are maintained by the CCRM Quality Manager and the office of the ADRAS.

The CCRM Quality Manager meets with the principal investigators heading EPA Region III projects at least annually to review their data and data management protocols. After review, the CCRM Quality Manager documents any concerns in writing and presents them to the principal investigator. The investigator responds with a plan to address any issues or shortfalls in the program data management. In cases where the CCRM Quality Manager is the principal investigator on an EPA Region III grant, the CCRM Director oversees this process.

The CCRM Quality Assurance Manager is responsible for addressing with the principal investigator any findings that result from an EPA assessment/audit. He or she meets with the principal investigator and EPA representatives to determine and document the procedures outlined for correction of any findings and tracks the completion of the corrective action as well as coordinates the preparation of a final response to the EPA.

At least once per year, generally coinciding with the annual internal audit, the Center Management conducts a review of the quality system to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review takes account of reports from managerial and supervisory personnel, the outcome of recent internal audits, any assessments by external bodies, the results of proficiency tests, any changes in workload, feedback from user groups, corrective actions and other relevant factors.

QUALITY IMPROVEMENT

It is the responsibility of the CCRM Quality Manager or designee to identify, implement, and evaluate the effectiveness of the CCRM quality improvement activities. Based on EPA mandates from “EPA Requirements for Quality Management Plans” (EPA QA/R-2), the CCRM Quality Manager is responsible for:

Ensuring that conditions adverse to quality are:

- prevented,
- identified promptly including a determination of the nature and extent of the problem,
- corrected as soon as practical, including implementing appropriate corrective actions and actions to prevent reoccurrence,
- documenting all corrective actions, and
- tracking such actions to closure;
- encouraging staff at all levels to establish communications between customers and suppliers, identify process improvement opportunities, and identify and offer solutions to problems.

Documentation of these actions is in the form of stored annual reports and reviews. Review of these documents is performed by committee on a periodic basis.

A quality assurance report is prepared as part of project final reports. The focus of the report is to highlight any factors that contribute to the uncertainty or reliability of the research conclusions. The report details the nature and frequency of problems that were (1) prevented, (2) discovered, and (3) corrected.