

## SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Zener Electrical & Electronics, P.O. Box 389, Dubai, U.A.E.; and P.O. Box 3905, Abu Dhabi, U.A.E.; and Zener Electrical & Electronics Service Building, Liwa Street, Umm al Nar area, Abu Dhabi, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial .....	79 FR [INSERT FR PAGE NUMBER] 6/5/14.
	Zener Electronics Services, Al Sharafi Building, Khalid bin Walid Rd, Dubai, U.A.E.; and P.O. Box 389, Dubai, U.A.E.; and P.O. Box 3905, Abu Dhabi, U.A.E.; and Plot S20206, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial .....	79 FR [INSERT FR PAGE NUMBER] 6/5/14.
	Zener Marine, P.O. Box 389, Dubai, U.A.E.; and Al Quoz Warehouse, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial .....	79 FR [INSERT FR PAGE NUMBER] 6/5/14.
	Zener Navcom, P.O. Box 389, Dubai, U.A.E.; and P.O. Box 3905, Abu Dhabi, U.A.E.; and Plot S20206, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial .....	79 FR [INSERT FR PAGE NUMBER] 6/5/14.
	Zener One Net, P.O. Box 389, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial .....	79 FR [INSERT FR PAGE NUMBER] 6/5/14.

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Dated: May 30, 2014.

**Matthew S. Borman,***Deputy Assistant Secretary for Export Administration.*

[FR Doc. 2014-13149 Filed 6-4-14; 8:45 am]

**BILLING CODE 3510-33-P****DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****15 CFR Part 997****[Docket No. 120813326-4163-02]****RIN 0648-BC18****U.S. Integrated Ocean Observing System; Regulations To Certify and Integrate Regional Information Coordination Entities**

**AGENCY:** U.S. Integrated Ocean Observing System Program Office (IOOS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Integrated Ocean Observing System Program Office, led by the National Oceanic and

Atmospheric Administration (NOAA), issues this final rule to implement provisions of the Integrated Coastal and Ocean Observation System Act of 2009 (ICOOS Act). Among other things, the ICOOS Act directs the Interagency Ocean Observation Committee (IOOC) to develop and approve certification criteria and procedures for integrating regional information coordination entities (RICEs) into the National Integrated Coastal and Ocean Observation System (System). This rule accomplishes that goal. This rule also implements the provisions of the ICOOS Act establishing that certified entities integrated into the System are, for the purposes of determining liability arising from the dissemination and use of observation data, considered part of NOAA and therefore their employees engaged in the collection, management, and dissemination, of observation data in the System receive the same tort protections for use of that data as Federal employees.

**DATES:** Effective date: July 7, 2014.

**ADDRESSES:** Copies of the final rule are available upon request to U.S. Integrated Ocean Observing System Program Office, 1100 Wayne Ave., Suite 1225, Silver Spring, MD 20910. The final rule

can also be viewed on the Web and downloaded at <http://www.ioos.noaa.gov/certification/>.

**FOR FURTHER INFORMATION CONTACT:**

Dave Easter, U.S. Integrated Ocean Observing System Program Office, at (301) 427-2451.

**SUPPLEMENTARY INFORMATION:****Background**

The Integrated Coastal and Ocean Observation System Act of 2009 (Pub. L. 111-11) (ICOOS Act or Act) (codified at 33 U.S.C. 3601-3610) directs the President, acting through the National Ocean Research Leadership Council (Council), to establish a National Integrated Coastal and Ocean Observation System (System). The System must “include[] in situ, remote, and other coastal and ocean observation, technologies, and data management and communication systems, and [be] designed to address regional and national needs for ocean information, to gather specific data on key coastal, ocean, and Great Lakes variables, and to ensure timely and sustained dissemination and availability of these data.” 33 U.S.C. 3601(1). Another purpose of the System is “to fulfill the Nation’s international obligations to

contribute to the Global Earth Observation System of Systems and the Global Ocean Observing System.” 33 U.S.C. 3601(1) and 3603(a).

The System is built upon a national-regional partnership, with contributions from both Federal and non-Federal organizations, promoting the quick and organized collection and distribution of ocean, coastal, and Great Lakes data and data products to meet critical societal needs. System data is used by both governmental and non-governmental concerns, to, among other things, “support national defense, marine commerce, navigation safety, weather, climate, and marine forecasting, energy siting and production, economic development, ecosystem-based marine, coastal, and Great Lakes resource management, public safety, and public outreach training and education.” It is also used to promote public awareness and stewardship of the Nation’s waterways, coasts and ocean resources, and to advance scientific understanding of the use, conservation, management, and understanding of healthy ocean, coastal, and Great Lake resources. 33 U.S.C. 3601(1)(A)–(C).

The ICOOS Act directs the Council to establish or designate an Interagency Ocean Observation Committee (IOOC). In 2010, the Joint Subcommittee on Ocean Science and Technology (JSOST), acting on behalf of the Council, established the IOOC. The IOOC replaced, and assumed and expanded the role of its predecessor, the Interagency Working Group on Ocean Observations, which was originally established by the JSOST under the Ocean Action Plan.

Under the ICOOS Act, the IOOC must “develop contract certification standards and compliance procedures for all non-Federal assets, including regional information coordination entities, to establish eligibility for integration into the System.” 33 U.S.C. 3603(c)(2)(E). To create the certification criteria, the IOOC chartered two working groups consisting of subject matter experts on IOOS data partners and regional entities to draft recommended certification criteria. The recommended draft criteria were approved by the IOOC in October 2011 and released for public input. After a sixty-day public comment period and adjudication of public input, the IOOC drafted final certification criteria.

In developing certification criteria, the IOOC focused on identifying the governance and management criteria a RICE—organizations that coordinate regional observing efforts; manage and operate observing assets; manage and distribute data; and engage user groups

in product development—must have in place to allow NOAA to coordinate non-federal assets for the purposes of the ICOOS Act. The IOOC certification standards ensure the necessary policies, standards, data, information, and services associated with eligibility for integration into the System are appropriately established, coordinated, overseen and enforced.

This rule establishes the criteria and procedures for how RICEs can apply and become certified for and integrated into System. Integration into the System formally establishes the role of the RICE and ensures that the data collected and distributed by the RICE are managed according to the best practices, as identified by NOAA.

Additionally, under the ICOOS Act, employees of RICEs that NOAA has certified and incorporated into the System who gather and disseminate information under this Act are, for the purposes of determining liability arising from the dissemination and use of observation data, considered to be part of NOAA. In other words, they are federal employees for the purposes of tort liability relating to their work directly related to the System. Only those non-federal entities that agree to meet the standards established under the process described in the ICOOS Act, and that are designated by NOAA as certified entities in the System, will be considered as “certified” for purposes of these regulations.

This rule satisfies the ICOOS Act requirement that NOAA, as the lead Federal agency for implementing the System, “promulgate program guidelines to certify and integrate non-federal assets, including regional information coordination entities, into the System.” 33 U.S.C. 3603(c)(3)(C). Accordingly, it details the compliance procedures and requirements for certifying RICEs that satisfy the IOOC-approved certification standards.

Among other things, to become certified, RICEs must provide NOAA with information about their organizational structure and operations, including capacity to gather required System observation data. They must also document their ability to accept and disburse funds and to enter into legal agreements with other entities. RICEs must have by-laws, accountability measures governing boards and an explanation of how they are selected, and be able to provide information about RICE diversity, user feedback processes, and transparency. Moreover, RICEs must submit to NOAA a strategic operation plan to ensure the efficient and effective administration and operation of programs and assets to

support the System, and agree to and actually work cooperatively with other governmental and non-governmental entities to the benefit of the System. Importantly, an application for certification must include a description of the RICE’s management of ongoing regional system operations and maintenance. The RICE must illustrate its standard operating procedures for ensuring the continued validity and maintenance of equipment used; strategies to enhance the System. Additionally, a RICE must also provide a Data Management and Communications Plan documenting how the RICE maintains and controls data quality and distribution. Certification lasts for five years, after which time a certified RICE must apply for re-certification.

These regulations apply to the certification of RICEs only. Further regulations will be developed by NOAA to provide certification for other non-federal assets that do not meet the definition of RICEs.

#### Differences Between the Proposed Rule and the Final Rule

The Administrative Procedure Act (APA) notice-and-comment process (5 U.S.C. 553) contemplates that changes may be made to the proposed rule without triggering an additional round of public notice and comment so long as the changes are “in character with the original scheme” and are of a type that could have been reasonably anticipated by the public (i.e., a logical outgrowth of the proposal or comments received) (*Foss v. National Marine Fisheries Service*, 161 F.3d 584, 591 (9th Cir. 1998); *Chemical Mfrs Ass’n v. United States Environmental Protection Agency*, 870 F.2d 177 (5th Cir. 1989)). The differences from the proposed rule text, published in July 2013 (78 FR 39638) and this final rule, including the basis for changes, are summarized as follows:

A. NOAA added a definition of “Equipment” to § 997.1 to clarify the extent of requirement § 997.23 (d)(4)(i). The new language defines equipment “as a tangible asset that is functionally complete for its intended purpose and has a capital cost of over \$5000. Both individual sensors and collections of sensors on a platform are considered equipment and are subject to the \$5000 minimum cost.”

B. NOAA revised § 997.13(c) to now require a RICE to notify NOAA only when substantive changes are made to its organizational structure or Strategic Operational Plan, rather than when any changes are made to the details of the structure or Plan as published in the

proposed rule. There were a number of comments submitted that stated the proposed language would be onerous for a RICE. NOAA's intention with this requirement is to be notified and approve significant changes to the RICE's management and operational practices, not to be involved in the day to day operations of the RICE.

C. NOAA revised § 997.15(a) to remove the language allowing NOAA to conduct an audit without notice, and to now indicate that NOAA will work with the RICE on the timing and process for the audit. The intention of the audit is not punitive, but more evaluative and is consistent with language in the ICOOS Act requiring that NOAA, as the lead federal agency for the System, shall develop and implement a process for the periodic review and evaluation of the RICEs (Sect. 12304(c)(3)(H)).

NOAA's desire is to work with the RICE to review and evaluate the RICE's procedures with a goal to improve effectiveness and maintain credibility.

D. NOAA revised § 997.15(c) to extend the time available to request in writing that NOAA reconsider its intent to decertify the RICE or notify NOAA in writing of the corrective action(s) taken, from 30 days to 45 days.

E. NOAA added language to § 997.21(b)(3) to clarify that if a RICE has a conflict of interest policy that requires a Board member recuse themselves from funding decisions only when the decision may result in the Board member or a direct family member would benefit financially. NOAA recognizes that the ocean and coastal observing community is small and the proposed language would unnecessarily restrict Board member participation in decision-making if interpreted broadly.

F. NOAA revised § 997.23(d)(1) and (2) to delete the references to products and services that the system will deliver. NOAA received several comments stating that the focus of the Strategic Operational Plan should be on the process and desired outcomes, not the assets, products, and deliverables. NOAA agrees that the describing the RICE's processes to deliver quality data and desired outcomes is more valuable than specific products and services, that may change over the five year duration of certification.

G. NOAA revised § 997.23(d)(4)(i–ii) to clarify its requirement for the calibrating validating, operating, and maintaining equipment owned and/or operated by the RICE, and for maintaining equipment inventories, shipping logs and instrument history logs for equipment owned and/or operated by the RICE. NOAA agrees

with the comments on the subjective nature of the word "ensure" and has deleted this language. NOAA has also defined equipment in § 997.1, clarifying the extent of the requirement. NOAA's intent is that for assets owned and/or operated by the RICE, the RICE should describe a standard operating procedure for equipment maintenance according to best practices. NOAA's intent is not to dictate the required actions of the RICE, only that the RICE must have a standard operating procedure in place. For assets financially supported by the RICE, fully or partially, but operated by a subcontractor, the RICE should instruct subcontractors to follow best practices and should mandate that equipment maintenance reports should be available periodically or by request.

H. NOAA revised § 997.23(f)(3) to add language clarifying that a RICE is not responsible for performing or describing the quality control procedures for data the RICE obtains from a federal data source. NOAA received several comments stating that it would be unreasonable to require RICEs to perform additional quality control procedures on data federal agencies have deemed suitable for public use. While NOAA's intention is that all the data made available by the RICE is quality controlled, it does not see the necessity of applying additional quality control procedures to data these agencies have distributed for use. NOAA added language to clarify that the RICE must use QARTOD quality control procedures for those data with approved QARTOD manuals. This requirement is consistent with the ICOOS Act requirement that NOAA shall implement protocols and standards approved by the IOOC. Lastly, NOAA deleted the examples of different procedures that may be used in the quality control. For variables without documented QARTOD procedures, the quality control procedures are subject to the judgment of the RICE until QARTOD standards become available.

I. NOAA deleted the requirement that a RICE outline their plan and strategies for diversifying their funding sources and opportunities (proposed as § 997.23(g)(2)). NOAA received numerous comments that this requirement was not relevant to integrating a RICE into the System. Although NOAA encourages certified RICEs to pursue diversified funding sources and opportunities, it agrees that this requirement was not relevant to being integrated into the System and NOAA's intent is that the certification is not connected to any specific funding opportunities or existing awards.

J. NOAA revised § 997.23(d)(3) and § 997.23(f)(1)(i) to allow a RICE to identify more than a single individual for each of the positions described in these sub-sections. NOAA received several comments that not all RICES have a single individual responsible for observations system management across the region and/or data management across the region. Although NOAA has eliminated the limit on the number of individuals a RICE may identified for each of these positions, these individuals must still satisfy the requirements listed in § 997.26(c) to be considered employees of a RICE as defined in the rule.

K. NOAA revised § 997.25(c) to clarify that a RICE only needs to submit to NOAA the documentation on its annual operating and maintenance costs upon request. NOAA recognizes the additional reporting burden that an annual reporting requirement would impose and has modified its approach, while still maintaining NOAA's ability for fiscal oversight as required in the Act.

## Responses to Public Comments

NOAA published the Notice of Proposed Rulemaking on July 2, 2013 soliciting public comments until August 1, 2013. All written and verbal comments received during the public comment period were compiled and grouped into eight categories. Similar comments from multiple submissions have been treated as one comment for purposes of response. NOAA considered all comments and, where appropriate, made changes that are reflected in this final rule. Several commenters expressed concern about the rule under the Regulatory Flexibility Act and those comments are addressed further in the "Classification" section below. Substantive comments received are summarized below, followed by NOAA's response.

## Organizational Structure

*Comment 1:* Many Governing Board members have direct interest in the operations of the RA. If the rule is interpreted so that Board members whose institutions receive any funding from the RA would have to recuse themselves on any funding decisions, then it would be impossible to achieve a quorum. Perhaps the conflict of interest could be defined as applying to a council member receiving funds that benefit their own financial situation or that of their family members.

*Response 1:* NOAA agrees that the definition of the term "conflict of interest" may have the potential to create unintended consequences, and

has revised the term at § 997.21(b)(3) to indicate that a conflict of interest occurs when actions benefit a Board member's financial situation or that of their family members.

**Comment 2:** We request more clarity on definition of "solicits and receives advice on participant diversity, etc." The requirements stated here seem redundant with requirements which follow in (b)(5)(iii) with the exception of the term "advice." This paragraph also lacks supporting guidance about what would be considered sufficient documentation to demonstrate compliance.

**Response 2:** The objective of the requirement to solicit and receive advice on participant diversity is to show that the organization is actively soliciting feedback on their priorities and organizational structure. This requirement is different from the requirements in § 997.21(b)(5)(iii), in that the requirement in § 997.21(b)(3) seeks information on how the RICE solicits their partners for feedback on the RICE organizational structure, whereas the requirement in § 997.21(b)(5)(iii) asks for feedback to gauge the effectiveness of the organization.

When possible, NOAA has provided supporting guidance about what it considers sufficient documentation for approval within this rule, particularly when it considers doing so critical to defining the requirement. In addition, NOAA will publish guidance on complying with the requirements when the Final Rule is published. For this particular requirement, there is no "standard" for approval other than describing how and with what frequency the RICE solicits and receives advice.

**Comment 3:** Establishing a membership policy that "strives for diversity" is something that is difficult to demonstrate aside from a statement to the effect. This is an example of a requirement that appears to be outside the scope of necessary elements for certification. If that is not the case, the proposed rule must be modified to define "diversity" clearly and provide more information about the minimum necessary requirements.

**Response 3:** The rule identifies "strives for organizational diversity" as including intra-regional representation and addresses interests from both the public and private sectors. The objective of this requirement is to ensure that a RICE avoids the establishment of a limited and restricted organization that addresses a narrow set of user needs. This is consistent with the ICOOS Act language that states a RICE shall work

cooperatively with a variety of entities and consider the needs of multiple users within the region. Because this is clear in this final rule, no additional language is needed.

#### Strategic Operational Plan

**Comment 4:** The requirements for the SOP could be streamlined as some pieces of information are requested multiple times. Both the Development Strategy and the Budget Plan ask for information regarding how the RAs make decisions to support the system and for guiding funding decisions. Recommendation: Combine the elements for the Development Strategy and the Budget Plan together to make a more streamlined and coherent document.

**Response 4:** While § 997.23(e)(1) and § 997.23(g)(3) are logically related, each guideline asks for different levels of detail. § 997.23(e)(1) asks for the RICE to describe an approach for prioritizing new and possibly competing priorities. § 997.23(g)(3) asks the RICE for a budget plan which explains/defends the RICE's decisions for funding based on RICE priorities. For this reason, NOAA makes no changes to the proposed language.

**Comment 5:** As written, there are many requirements that are excessive or in need of clarification to demonstrate they are not excessive in application to RICES that have a mix of assets supported financially by different sources. The elements required for certification must only be those necessary to achieve the stated purpose of the proposed rule: To integrate RICES into the National Integrated Coastal and Ocean Observation System.

**Response 5:** NOAA maintains that the rule represents the minimum requirements for certification and integration into the System, based on the ICOOS Act language and the approved IOOC certification criteria. As part of the rule development process, NOAA performed a review of existing RICE documentation and operating procedures, and found that those documents can be reasonably adapted to meet the requirements written in the rule.

**Comment 6:** The focus of the Strategic Operational Plan (SOP) should be on the process and desired outcomes, not the assets, products, and deliverables. It is too restrictive and binding to presume that specific products should/will be delivered. Instead, develop SOPs that document processes, such as describing approaches to ensure documentation of QA/QC procedures in metadata.

**Response 6:** NOAA agrees with the comment that the focus of the Operational Plan should be on the

process and desired outcomes. The intent of the Operational Plan is to identify, at a high-level, how the RICE manages and operates the integrated system to achieve the desired outcomes. NOAA agrees that over the five year duration of certification, the assets, products, and deliverables that contribute to the system may change, and new approaches may be preferred to meet its objectives. NOAA's intent is that the RICE clearly identify the processes it has in place to achieve its desired outcomes, and amended the text in § 997.23(d)(1) and (2) accordingly.

**Comment 7:** This rule requires identification of the individuals responsible for observations system management and data management. Not all regional associations have a single individual who fills this role, which often is shared among a number of people. The certification, and therefore indemnification, process should acknowledge that NOAA has allowed regional association structures to develop that are best for each region. This section should be clarified to accommodate the current operational model and many RAs.

**Response 7:** NOAA accepts that RICE structures will vary; and has revised the rule to state that, for the purposes of indemnification and accountability, a RICE shall identify the individual(s) responsible for the coordination and management of observation data across the region, and as applicable, the individual(s) for observations systems management across the region. These individuals must still satisfy the requirements listed in § 997.26(c) to be considered employees of a RICE as defined in the rule.

**Comment 8:** Personnel evaluation (Rice Management & Data Manager) should not be part of certification.

**Response 8:** The ICOOS Act mandates that the RICE develop a strategic operational plan that ensures "effective administration" of programs and assets, "pursuant to standards approved by the Council". The primary purpose of this guideline is to ensure that (1) the RICE has a process in place for evaluating the capabilities of key personnel and (2) the people hired can perform the duties required. We do not believe that requesting a CV is excessive as Federal agencies routinely require CVs in grant proposals submissions, federal advisory committee nominations, etc., and therefore is not adopting the commenter's suggestion.

**Comment 9:** In section 997.23(d)(4), an active maintenance oversight program would burden operators with submitting detailed maintenance records and protocols and would be a

significant new burden that may result in fewer assets and data streams being available to the System. This requirement would be too labor intensive for the description of minimal anticipated efforts and costs associated with certification outlined under Regulatory Flexibility Act section. Furthermore, the rules should be clarified to define what is meant by “ensure” and also provide an example of how the RICEs are to comply with this provision. RAs should be given flexibility in how they ensure that those responsible for managing hardware owned and operated by the RA (even partially) be calibrated, validated, operated, etc. For instance, it should be specified that providing links to established procedures addressing these issues at the operators’ institutions is sufficient to meet this requirement.

**Response 9:** NOAA has amended the rule based on reviewers’ comments of the subjective nature of the word “ensure” by removing the reference to “ensuring that those responsible for managing hardware” from this rule and simplifying the language in section 997.23(d)(4) to describe the standard operating procedures used for quality assurance processes. An example of how the RICEs are to comply with this provision is, for assets owned and/or operated by the RICE, the RICE should describe a standard operating procedure for equipment maintenance according to best practices. NOAA agrees that reviewing subcontractors’ inventories and equipment history logs would be overly burdensome; yet, the rule does not dictate the required actions of the RICE, only that the RICE must have a standard operating procedure in place. For assets financially supported by the RICE, fully or partially, but operated by a subcontractor, the RICE should instruct subcontractors to follow best practices and should mandate that equipment maintenance reports should be available periodically or by request.

**Comment 10:** Section 997.23(d)(4)(i) requires more definition. Equipment should be specifically defined as capital equipment, e.g., exceeding \$5000 in value with a shelf life of greater than three years. Also, Terms and Conditions to meet this requirement should be supplied by NOAA for inclusion in sub-awards from the RAs.

**Response 10:** NOAA agrees that § 997.23(d)(4)(i) requires clarification, and has amended the rule to include a definition for the term equipment, which includes a price floor of \$5000. This amount is used to be consistent with OMB Circular No. A-122, establishing principles for determining costs of grants, contracts and other

agreements with non-profit organizations. A-122 defines equipment as “nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-profit organization for financial statement purposes, or \$5000.” NOAA stresses that even though documented procedures are not required for certification for assets below the price floor, RICEs should maintain all equipment according to industry best practices.

NOAA disagrees that it should supply Terms and Conditions for this requirement. NOAA has taken a position, based on feedback from the RICEs during the development of the rule, that where possible, this rule shall avoid being too prescriptive, so as to allow each RICE to address the requirements as they see best, given their unique situation. NOAA believes that it is the responsibility of each RICE to work with their legal counsel and fiscal agents to develop contract language that meets their specific needs.

**Comment 11:** Section 997.23(f) of the Strategic Operational Plan (Data Management and Communication Plan) lists six actions. Shall these actions be implemented simultaneously, or can the regional or local entity prioritize? Data quality control procedures vary from entity to entity. It is going to take time and effort to bring everyone to the same level.

**Response 11:** All actions must be sufficiently addressed to achieve certification. The order by which the actions are addressed is at the discretion of the RICE.

**Comment 12:** The rules should state how the U.S. IOOS Program intends to handle model output, observational grids, or project level GIS data layers.

**Response 12:** Through this rule, NOAA is not providing guidance on model output or any other non-observational data in the certification requirements at this time. The IOOS Program Office welcomes a discussion with all IOOS partners to develop best practices related to these other types of information, but any proposed standards/processes would not be tied to certification.

**Comment 13:** Will a program that wants to contribute data to an IOOS-supported regional data portal be expected to adhere to an IOOS-sponsored or supported DMAC requirement for metadata (e.g., ISO 19115 and SensorML) and QA/QC (e.g., QARTOD)? The rule provides examples of qualified procedures (e.g., QARTOD, JCOMM/IODE, scientific literature), but

we interpret these as examples and not mandates. If adherence to the specific standards mentioned is mandatory, this will discourage many programs from sharing data through IOOS.

**Response 13:** NOAA has clarified the guideline to address the commenters’ concerns. For variables with documented QARTOD procedures, these procedures must be implemented and referenced on the RICE’s Web site. For variables without documented QARTOD procedures, the quality control (QC) procedures are subject to the judgment of the RICE until QARTOD standards become available, but QC of some type must be performed and referenced. The RICE may choose to make data contributors responsible for QC and reference the procedures in the DMAC plan, or may perform the QC itself. Because the RICE can choose to perform QC of the data, we believe this requirement should not substantially deter other programs from sharing data through IOOS. Certification does not specifically mandate any DMAC requirements for metadata.

**Comment 14:** Greater flexibility is needed in the regulations to allow the wide spectrum of contributions to IOOS. The RICE should be allowed to provide data of various levels of quality to the system as long as the provenance of the data being discovered and exposed is made easily accessible through metadata that allows the user to assess the veracity and quality of the data.

**Response 14:** Since NOAA will provide the RICE with liability protection for activities related to its work on the dissemination and use of observation data, it is important that proper data management practices are in place and followed to mitigate the risk of liability. At a minimum, all data distributed by the RICE must be quality controlled either by the RICE or by the entity providing data to the RICE. This is the minimum step necessary to ensure data quality. While the RICE may include a description of the provenance of the data in the metadata, this does not replace the need to perform quality control on all data.

**Comment 15:** Documenting the quality control and assurance procedures for each individual data stream will be repetitive and time consuming. Rather, it would be more realistic to document the quality assurance protocols developed by individual data providers/sources. Overall, additional guidance detailing best practices and real world approaches to applying QC in an operational setting would be useful due to the large number of data streams that a RICE makes available.

*Response 15:* Since a data source can produce multiple data streams, and since each data stream must be quality controlled, the language was not changed. In practice, the RICE does not need to document the quality control procedures for each and every data stream. Data streams with similar QC procedures can be combined into larger categories, and the QC procedures for these larger categories can be described in the RICE's Data Management Plan as part of the certification application. The comment also asks for guidance on real world approaches to applying QC in an operational setting. The new rule language mandates QARTOD procedures for variables which QARTOD manuals are available. These manuals establish a framework that addresses real time collection and processing of these data through QC tests with codeable instructions. For variables which QARTOD manuals do not exist, quality control procedures are subject to the judgment of the RICE, providing flexibility to the RICE.

*Comment 16:* Federal agencies collecting ocean data that are distributed through RICE portals should have the QC responsibility for their own data streams. It would be helpful if the certification document clarified the nature of observing programs and networks that are the result of federal-regional partnerships, particularly CDIP and NERRS.

*Response 16:* NOAA does not expect that RICES should perform their own QC on Federal data sources, but are encouraged to reference existing Federal QC procedures if the RICE makes these data available. For CDIP and NERRS, these programs are considered largely Federal and thus the RICE would not be required to perform QC on these data, if they are redistributing that data as is. In the case of CDIP, if a RICE deploys a wave buoy and provides that data independently on the RICE data portal, QC must be performed according to QARTOD standards, if available, or documented procedures if QARTOD manual is not available. For other federal-regional partnership programs that may exist currently or in the future, RICES and the IOOS Program Office will assess on case by case basis.

*Comment 17:* Some Federal data sources serve RICE data, and it seems unreasonable for IOOS to require RICES to document or enforce additional standards and protocols for data that is 'qualified' to be presented via these other federal portals.

*Response 17:* Within NOAA, when a Federal center receives a RICE data source, the QC procedures of that center are required to ensure NOAA meets its

own indemnification. For example, in the case of NDBC, mentioned in the comment, NDBC applies QC procedures before making the data public, so in effect, the RICE data is not "qualified as is" to be disseminated via NDBC. Further, the data that NDBC rebroadcasts is only a subset of the total RICE data. Finally the process is that the RICE data is simultaneously disseminated to NDBC and the RICE data portal. The RICE does not wait until NDBC has performed the QC to disseminate their data. Therefore, NOAA maintains for the purpose of certification, the RICE must separately perform quality control on the data.

*Comment 18:* We request that the US IOOS Program Office host discussion sessions with the IOOS community about the IOOS standards for metadata and quality assurance and how all the individual parts fit together.

*Response 18:* NOAA agrees discussion sessions would be beneficial. The IOOS Program Office hosted annually since 2008 a collaborative working session with the Regional Association Data Managers where quality control and metadata standards have been discussed. Specifically at the Data Management and Communications Meeting in September, 2013 in Silver Spring a session was dedicated to the implementation of IOOS certification requirements and data management requirements from NOAA. For the last three years, at both the Spring and Fall IOOS association meetings, data management has been on the agenda. These topics have been discussed at a number of IOOS Regional Association meetings and it is almost always requested and discussed at the individual regional meetings. The IOOS Program Office will continue to participate/host additional discussion sessions.

*Comment 19:* The RICE cannot exert much control over partners with little or no financial support from IOOS. The inclusion of a limited set of metadata and QA/QC flags transmitted to the RICE is not unreasonable from non-IOOS funded data streams. However, data generated with IOOS funding would be a different matter as the RICE would have more control over those operations and data processing steps. RAs should have the option of serving data from non-federal providers who don't receive financial support from the RAs without going through the same level of QC and oversight that they provide for organizations they do support. A suggestion would be to have different categories of data streams on the portal: Federal, RA-supported, and other. Data streams would be clearly

identified as to their source and which category they fell in, and metadata would be provided to allow users to decide which data streams were adequate for their use.

*Response 19:* NOAA disagrees that the RICE should have the option of serving data from non-federal providers who don't receive financial support from them without going through the same level of QC and oversight that they provide for organizations they do support. QC must be performed on all data that the RICE makes available, regardless of funding source. The quality control requirements are not overly burdensome since the rule does not require that the RICE partners perform their own QC. Rather, the RICE is responsible for QC and may assign the responsibility to its partners or may choose to perform the QC itself. NOAA does not agree with the idea of developing data categories based on financial contribution from the RICE. The premise of IOOS is to leverage capabilities from a variety of Federal, non-Federal, academic, industry, etc. sources in order to increase the availability and use of coastal and ocean information. Data categories based on funding would result in confusion and would oppose the concept of open data sharing through the RICE.

*Comment 20:* It is not clear why the "RICE's plans and strategies for diversifying funding sources and opportunities;" is relevant to integration into the national program. This should not be part of a federal certification process.

*Response 20:* NOAA agrees that the requirement is not relevant to integration into the national program, and has removed this requirement from the rule.

#### Gaps Identification

*Comment 21:* Certification should not establish new unfunded mandates. The current certification process establishes the need for an online "Regional Asset Inventory" that has previously not been required.

*Response 21:* The rule sets minimum requirements for certification based on the ICOOS Act language and the IOOC approved certification criteria. NOAA does not agree that the rule establishes unfunded mandates, as the pursuit of certification is voluntary. Regarding the Gaps Identification requirement referenced in the comment, the rule does require the establishment of a regional asset inventory, but states that a "database or portal accessible for public viewing" could demonstrate that a RICE meets this requirement.

### *Financial Oversight*

*Comment 22:* Requiring the RICE's subcontractors document operating and maintenance costs for their observing platforms that contribute data even when IOOS funds may not contribute to that operation or maintenance may discourage participation in the system. Certification should be a five year process with no pieces in between. Operating costs should not be required annually.

*Response 22:* A RICE is only required to document its annual operating and maintenance costs for assets owned and/or operated by the RICE as defined. The annual financial information is intended to report on expenditures by the RICE. For example, in a RICE to subcontractor relationship, only the RICE funds to the sub-contractor would be included in the reports. Funds the sub-contractor receives from other entities would not be included in the report by the RICE. The annual budgets submitted by the RICE, as part of a cooperative agreement, will meet this requirement.

With respect to the commenter's concern that certification "should be a five year process with no pieces in between," NOAA revised § 997.25 (c) to clarify that the RICE need only submit the annual operating and maintenance costs upon request. While NOAA understands the desire to have manageable tasks associated with certification, it believes that although a RICE is certified, there should be measures in place to ensure accountability. The Act requires a RICE to "comply with all financial oversight requirements established by the Administrator, including requirements relating to audits." NOAA must be able to have a process, in addition to audits, to ensure fiscal oversight. Requiring the RICE to annually document its operations and maintenance costs, and providing those upon request, is one way to achieve this.

### *Civil Liability*

*Comment 23:* One of the main incentives for a Regional Association (RA) to apply for certification is for liability protection. The extension of liability protection to no more than three individuals doesn't seem to fulfill the sense of the ICOOS Act. It is not clear why limiting indemnification is relevant or necessary. The limitation of protection to three individuals should be removed so as to allow the RA to submit the names of all individuals responsible for operations, including Board members and contractors, to NOAA for review and approval. Civil

liability should not be limited when all affiliates are potentially at risk for legal action as well. This will lead to challenges recruiting Board members and the kind of staff members necessary to continue to develop the U.S. IOOS system at the regional level. Additional language is needed to explain the meaning and extent of "The individual is responsive to federal government control."

*Response 23:* NOAA agrees there may be more than three individuals who are responsible for RICE operations. NOAA has revised the rule, allowing a RICE to identify more than one individual responsible for each of these areas: Overall system management; observations system management across the region; and, management of data operations across the region. In order to be approved for certification, a RICE must demonstrate that these individuals are responsible for managing operations across the region, and are responsive to federal control.

The ICOOS Act associates civil liability to employees. While the ICOOS Act does not clearly define employee, causing some ambiguity about who qualifies for the extension of civil liability, the term employee does have specific meaning in Federal tort law. According to the Federal Tort Claims Act, and for the purposes of this rule, an employee of the government includes, "persons acting on behalf of a federal agency in an official capacity, temporarily or permanently in the service of the United States, whether with or without compensation." Given this definition, to be considered a RICE employee under this rule, an individual must be formally acknowledged by NOAA and that individual shall be responsive and accountable to NOAA.

In response to the comment suggesting that NOAA further explain the "meaning and extent of 'The individual is responsive to federal government control,'" NOAA has chosen to leave the language of this rule unchanged in order to retain flexibility in working with each RICE. This approach is necessary due to the variations in RICE organizational structures and the mechanisms available to NOAA to ensure RICE employee responsiveness. Since RICES by their nature operate through the extensive use of partnerships and non-traditional employee/employer relationships, this creates challenges in applying the definition of employee from Federal tort law.

NOAA has identified in the rule, those positions that most closely meet the intent of the meaning of employee from Federal tort law. The positions

identified in the rule have significant impact on, and are influential in, assuring the reliability of the data. As such they are in positions to mitigate the risk of liability arising from the dissemination and use of observation data. These positions work across the region and are accountable to the RICE and NOAA for data collection, dissemination, and use.

*Comment 24:* It is recommend that NOAA and the IOOS Program Office work with the regional associations to undertake a full review of the options available to limit the RICE's liability risk.

*Response 24:* NOAA is available to discuss the rule and how it will be implemented. NOAA understands the commenter's concern about a RICE's liability risk, but each RICE should seek its own legal advice.

*Comment 25:* Please clarify—do data providers or regional partners to GCOOS have to have individual contracts, leases, grants, or cooperative agreements with NOAA to be protected, or can their membership in GCOOS qualify them as protected from civil liability? We strongly encourage the latter to minimize costs and facilitate participation in the RICE and IOOS.

*Response 25:* While NOAA appreciates the RICE's concern about the liability status of their partners, certification is for the RICE alone and the extension of civil liability protection is to certified RICES and their employees only. Under the rule, employees of a RICE are defined as those individuals filling the positions identified in the rule and are the only individuals covered by the civil liability protection. Neither membership in a RICE or a contract, lease, grant, or cooperative agreement with NOAA is sufficient to qualify an entity, organization, or individual as protected from civil liability.

*Comment 26:* The benefits of certification are not clear. One is the extension of federal tort liability protection to two or three employees of a certified RICE. I say two or three because it is not clear that three are actually covered. § 997.30(c)(2) states that the individuals to be protected must be identified under § 997.23(d)(3), which only lists two positions.

*Response 26:* NOAA agrees that paragraph (c)(2) of the civil liability section is not clear and revised the section to account for all the individuals that may fill the three positions identified in § 997.23(d)(3) and § 997.23(f)(1) and to be consistent with the definition of Employee of a Regional Information Coordination Entity in the rule.

*Comment 27:* The primary responsibility of an employee and/or Board of Directors is to the corporation. As such, conceding power to another organization (NOAA) in oversight of RICE employees and/or contractors as required in the regulations (§ 997.30) has the potential for conflict of interest and is unacceptable. Compliance with program requirements is already legally covered through the Cooperative Agreements.

*Response 27:* In order for the federal government to afford civil liability to an employee, there must be a relationship between the federal government and the employee characterized by responsiveness and accountability. Certification requirements are separate and distinct from the cooperative agreements, which are awarded through a competitive process. A funding agreement with NOAA is not a requirement for certification. Having a stand-alone certification process ensures that NOAA has a mechanism for working with certified RICES.

*Comment 28:* Shall a non-federal employee who is participating in the System, being paid one month salary by contract (ICOOS, etc.) and eleven month by his or her local entity, be considered, with respect to tort liability, an employee of the Federal Government?

*Response 28:* The extension of civil liability protection is to employees of certified RICES only as defined in the rule.

*Comment 29:* If the local entity has a "Disclaimer" on its own Web site for data users that it does not accept liability for any damages or misrepresentation caused by inaccuracies in the data or as a result of changes to the data caused by system transfers, transformations, or conversions, nor is there responsibility assumed to maintain the data in any manner or form, will this Disclaimer contradict with the IOOS tort liability/civil liability?

*Response 29:* The grant of civil liability protection applies only to a certified RICE and its employees identified in § 997.26(c)(2). A disclaimer would not affect this status.

*Comment 30:* Switching the focus of certification to those activities that are 100% funded by IOOS could help simplify the limitation of what is covered under indemnification, without also limiting the number of potential individuals that could be impacted by legal action.

*Response 30:* The extension of liability coverage is to the RICE and its employees as defined in the rule, and is independent of funding amounts or sources that support the dissemination

and use of observation data. The certification process is separate from the competitive grants process that NOAA uses to fund the development of regional observing systems and the regional entities that coordinate this development.

#### *Certification Process*

*Comment 31:* The draft rules define "owned and/or operated" as an asset that is supported financially in part or full by the RICE. This implies that we would be required to meet these standards even, if we are providing only a small portion of the operational costs for an asset. We recommend that this section be reworded to be less stringent and that the definition of "owned and/or operated" be changed to an asset that is supported financially in full by the RICE.

*Response 31:* This rule clearly defines "owned and/or operated" as including any asset that is supported financially in part or in full by the RICE, regardless of the amount of this support. To be certified, a RICE must meet the standards for all assets that fall within this "owned and/or operated" definition, even if the RICE provides relatively little funding to support those assets. NOAA stands by this definition and disagrees with the comment suggestion that this definition "be changed to an asset that is supported financially in full by the RICE." In order to certify a RICE and extend liability protection under the Act, NOAA must ensure that all data distributed by that RICE, regardless of funding source or amount, meets quality assurance standards.

*Comment 32:* The description also fails to state that there will be one RICE per region. NOAA should clarify the language to state that, "Existing Regional Associations in IOOS will be prioritized for the designation as the single RICE for IOOS in the region."

*Response 32:* NOAA cannot accept the suggested text because it is inconsistent with the Act and would give preferential treatment to some applicants over others. The Act defines RICES as including Regional Associations, but does not limit RICES to only these entities. Further, the Act makes no mention of limiting the number of RICES by geography or any other criteria. NOAA must review all applications it receives and objectively evaluate them against this rule's requirements.

NOAA is committed to having regional entities that cover the entire U.S. ocean and Great Lakes coasts. These regional entities are an important component of the overall IOOS system.

NOAA has worked closely with the eleven regional associations that belong to the IOOS Association to develop the organizational and observing system capacity to serve in the role of a RICE, and expects that these entities will be well suited to become certified RICES should they choose to apply. However, NOAA is required to consider all the applications that it receives for certification as a RICE.

*Comment 33:* Provide guidance on what happens if an RA chooses not to be certified or becomes decertified. Would they still be "integrated into the System"? If a RICE is decertified, will they risk losing funding or other benefits?

*Response 33:* Certification is the formal process for incorporating a RICE into the System. A regional association that chooses to not pursue certification will not be formally incorporated into the System. If a RICE is decertified, that entity will no longer be incorporated into the System and will not receive the benefits of being a certified RICE. The certification process is separate from the competitive grants process that NOAA uses to fund the development of regional observing systems and the regional entities that coordinate this development. It is not the intent of NOAA to tie certification to the competitive funding program.

*Comment 34:* Section 997.13(c) requires written notification from the RICE to NOAA and approval by NOAA of any changes to the "details originally provided" for the Strategic Operational Plan (SOP). This language is too prescriptive and burdensome. An annual statement could be filed outlining any substantive changes at an RA. Change 997.13(c) to read: A certified RICE shall provide NOAA with written notification of the RICE's intention to substantively change its organizational structure or SOP.

*Response 34:* NOAA concurs that the original language is too prescriptive and has revised § 997.13(c) to now require a RICE to notify NOAA only when substantive changes are made to its organizational structure or Strategic Operational Plan, rather than when any changes to the details of the structure or Plan as published the proposed rule.

*Comment 35:* I recommend that the RICES be given 45 days, not 30, to request in writing a reconsideration of NOAA's decision to decertify or to notify NOAA of corrective action.

*Response 35:* NOAA concurs and, based on this public comment, has revised § 997.15(c) to now state that RICES have 45 days to request reconsideration of NOAA decision.

*Comment 36:* The rule should be amended to require that NOAA inform RICEs of the audit procedure that will be used, and also to provide adequate notice of its intent to audit. Under what conditions may NOAA audit a RICE? Will “just cause” be required to audit a RICE or can it be done randomly?

*Response 36:* NOAA concurs that a RICE be given notice of an audit and that NOAA will coordinate with the RICE on the timing and process for the audit. Section 997.15(a) has been revised to reflect this policy. NOAA reserves the right to conduct audits as needed to ensure the integrity of the certification process and will work with the RICEs to mitigate potential impacts of the audit.

*Comment 37:* The rules should acknowledge that compliance will depend on available resources. Each year, the IOOS Program Office works with individual RAs on descoping the annual budgets. This process should be used to fulfill this requirement. Approval by the U.S. IOOS Program Office of the annual spending plans through the descoping process should account for compliance with these regulations.

*Response 37:* Each organization must decide whether they are going to pursue and maintain certification based on their available resources. Certification is not dependent on any funding amount or agency funding opportunity, and as such, compliance with the certification requirements cannot be re-evaluated year to year based on funding levels. NOAA agrees that existing documents can serve the purpose of showing compliance with the certification requirements and has indicated this in section 997.20(b).

#### General Comments

*Comment 38:* Complying with this requirement would be a major new burden on our limited resources. NOAA is underestimating the time, effort, and expense that it will take to come into full compliance with the proposed regulations. The time anticipated to complete the application packet should be no more than one week (40 hours). We estimate it would take roughly 2–2.5 person-months effort for the initial submittal, ~1.5–2 person months every 5 years for recertification as requirement change, ~1 person month each year for annual compliance, and an unknown amount of time to comply with audit requirements. Any cooperative agreement with NOAA should be adjusted to reflect these real costs.

*Response 38:* The estimate of two or two and one half person months (320–400 hours) effort for the initial submittal

is not far from the 293 hour estimate put forth in the proposed rule, and was done without the benefit of the rule implementation guidance that NOAA is developing. NOAA points out that this effort is only required every five years. We disagree with the estimate that annual compliance will require 160 hours of effort, and NOAA is committed to working with a RICE to mitigate the cost of any audit.

When estimating the amount of effort to submit an application, NOAA must include not just the time necessary to fill out the form and submit the application, but also the time estimated to meet the requirements for certification. This amount will vary depending on the relative maturity of the applicant organization.

Since no justification is given for the statement that the application packet should be no more than 40 hours, we can't respond to its viability.

NOAA disagrees with the comment that it should adjust its existing cooperative agreements with the entities that are interested in pursuing certification. Any applicant with a financial agreement with NOAA can direct their resources towards becoming certified. Through a series of cooperative agreements, NOAA has funded the eleven Regional Associations since FY 2005 to develop the organizational structure, operating procedures, and data management capacity necessary to serve in the role of RICEs. Certification is optional, and a Regional Association opting to pursue certification can re-prioritize existing resources to do so, since much of the effort, particularly the data management work, is consistent with their overall work plans established for these agreements. Finally, since application for certification is not mandatory, each organization can determine if the benefits of being certified is worth the cost.

*Comment 39:* This section should enumerate all potential benefits for a RICE for becoming certified.

*Response 39:* The potential benefits of a RICE becoming certified are identified in the “Background” and “Classification” sections in this rule.

*Comment 40:* The rule should clearly state that RICEs not seeking certification will not lose their future eligibility for funding, or the amount of funding they receive as a regional association within U.S. IOOS, or other penalties.

*Response 40:* U.S. IOOS will have regional entities that cover the entirety of the U.S. ocean, coast, and Great Lakes. These regional entities are an important component of the overall U.S. IOOS system. The certification process

is separate from the competitive grants process that NOAA uses to fund the development of regional observing systems and the regional entities that coordinate this development. The establishment of a certification process is a requirement of the ICOOS Act and creates the formal process for incorporating a RICE into the System. It is not the intent of NOAA to tie certification to the competitive funding program, nor is it NOAA's intent to favor one regional entity over another based on certification decisions.

*Comment 41:* In general it is unclear what level of detail is required to satisfy the certification criteria. Detailed and reviewed examples of what would pass the process would be very useful. With an inevitable turn-over of personnel at both the US IOOS program office and in the regions, it is important the certification rules be as clear as possible about the requirements.

*Response 41:* NOAA will publish certification guidance online at <http://www.ioos.noaa.gov/certification> within 30 days of publishing the final rule in the *Federal Register*.

*Comment 42:* Certification requirements should be in proportion to the scale of the existing programs. For example, current funding levels do not allow for the clearest organizational design and while RAs may desire to have an observing system manager current funding levels may not allow such a position to exist.

*Response 42:* This final rule sets minimum requirements for certification based on the ICOOS Act language and the IOOC approved certification criteria. NOAA understands that regional entities are unique and has avoided being prescriptive in the requirements when possible.

*Comment 43:* We recommend that you keep implementation requirements as simple as possible, and tie them to the existing 5-year cooperative agreement proposals and annual descoped proposals. Execution of the cooperative agreement, also having a life-span of five years, would therefore serve as certification and meet the requirements of the ICOOS Act.

*Response 43:* The certification process is separate from the competitive grants process that NOAA uses to fund the development of regional observing systems and the regional entities that coordinate this development. The establishment of a certification process is a requirement of the ICOOS Act and creates the formal process for incorporating a RICE into the System. It is an agreement between NOAA, as the lead agency for the System, and the RICE. The cooperative agreements that

fund the development of regional IOOS are an agreement between the IOOS Program under NOAA and the regional associations that have been awarded funding through the competitive funding opportunity offered by NOAA. NOAA agrees that existing documents can serve the purpose of showing compliance with the certification requirements and has indicated this in the rule.

*Comment 44:* The criteria should facilitate the use of ocean acidification research and monitoring for implementation of the Clean Water Act. RICEs should be informed of Clean Water Act water quality criteria and be required to provide their monitoring data and other relevant information to EPA, tribes, and states for use during their water quality assessments. Data quality protocols should be preapproved by EPA, tribes, and coastal states so that ocean acidification data can automatically be used for water quality assessments.

*Response 44:* The U.S. IOOS supports the free and easy access to data by all stakeholders interested in ocean acidification. Many of the regional associations and their partners are actively collecting and distributing ocean acidification data. These organizations are working closely with federal and non-federal partners on data collection and data management processes.

*Comment 45:* State and industry monitoring programs under the Clean Water Act should be adapted to collect data relevant for ocean acidification.

*Response 45:* This recommendation is outside the scope of the ICOOS Act and the certification of RICEs.

*Comment 46:* As written the regulations impose burdens that are likely to prevent many non-federal data providers from contributing their important assets to the IOOS System. I request that NOAA review the regulations and where possible within the mandate of the law to simplify them and narrow their scope so as to encourage participation in the building of the IOOS rather than discourage it.

*Response 46:* The rule sets minimum requirements for certification based on the ICOOS Act language and the IOOC approved certification criteria. It is not NOAA's intent to create disincentives to participation in the U.S. IOOS, but to establish formally, the organizational qualities of a RICE and ensure a level of data collection, management, and distribution practices are in place. NOAA followed the notice and comment requirements set forth in the Administrative Procedure Act in the development of this action. NOAA has

revised the rule based on the comments it received where possible, with the intent of improving the rule.

*Comment 47:* While many of the criteria related to governance might be good suggestions for organizational operations, they do not directly influence or improve the ability of a RICE to be "integrated into the System," particularly in the context necessary to support indemnification for the collection, dissemination, and use of observation data.

*Response 47:* The requirements in this final rule are responsive to the language in the ICOOS Act and the IOOC approved Certification Criteria. Section 12304(c)(4)(A) of the ICOOS Act identifies the requirements a RICE shall meet, including those related to an organizational structure. These are further developed in the IOOC Certification Criteria and form the basis for the requirements contained in this rule.

*Comment 48:* This rule does not reflect the range of efforts that comprise IOOS including the concept of a spectrum of research and operations that was embraced and the 2012 IOOS Summit. Not all aspects of RA systems are operational (§ 997.23(f)(4)). DMAC processes should include those for modeling which is not mentioned in the certification requirements.

*Response 48:* NOAA disagrees that this rule does not reflect the range of efforts that comprise IOOS. The rule makes several references to the different components that make up the System, such as in § 997.21(a) and § 997.23(c)(2). This rule sets minimum requirements for certification based on the ICOOS Act language, which includes references to the System Plan, and the IOOC approved certification criteria. While a new concept of a spectrum of research and operations was put forth at the 2012 IOOS Summit, this concept has yet to be formally recognized in the way the System Plan has.

The focus is on creating a process to certify a RICE and incorporate it into the System. NOAA acknowledges that the requirements are not inclusive of all the activities that a RICE might engage in, such as modeling. As mentioned in Response 12, NOAA is not providing guidance on model output or any other non-observational data in the certification requirements at this time. Since the extension of liability protection covers observational data, the DMAC requirements are limited to observational data. NOAA will consider including requirements for activities like modeling in the future.

*Comment 49:* Certification should respect the operational integrity and

independence of the RAs. One of the strengths of the RAs and benefits for NOAA is their ability to act nimbly and be responsive. The current regulations would curtail that ability.

*Response 49:* NOAA disagrees that this rule would curtail the ability of an RA to act nimbly and be responsive to regional issues and stakeholder needs. Since the comment provides no specifics on how the regulations would curtail the ability of the RAs to continue to act nimbly and be responsive to new priorities and needs, we cannot respond more substantially to it. NOAA has revised § 997.13(c) to now require a RICE to notify NOAA only when substantive changes are made to its organizational structure or Strategic Operational Plan, rather than when any changes to the details of the structure or Plan as published the proposed rule. NOAA must have in place a process to ensure accountability, but it does not intend to be involved in the day to day operations of the RICE.

*Comment 50:* We fear that the application of these rules, particularly on the data management and QA/QC process, may discourage data sharing, thereby setting back many of the gains made by the program to date and being counterproductive to the IOOS goal of increasing stakeholder access to data and fostering data discovery.

*Response 50:* NOAA has addressed some of the concerns received in the comments about the rule's data management requirements being onerous and discouraging data sharing by clarifying the rule requirements. The RICE may choose to make data contributors responsible for QC, or may perform the QC itself. Because the RICE can choose to perform QC of the data, we believe this requirement should not substantially deter other programs from sharing data through IOOS. Instead of being counterproductive to the U.S. IOOS goals and objectives, NOAA thinks the requirements for data quality assurance and quality control procedures strengthen the U.S. IOOS by ensuring data management practices are in place for all data that are distributed through the System.

*Comment 51:* We request that the US IOOS Program Office host discussion sessions with the IOOS community about the IOOS standards for metadata and quality assurance and how all the individual parts fit together.

*Response 51:* NOAA is happy to work with the IOOS community to discuss how standards for metadata and quality assurance, along with other data management processes fit together. The IOOS Program has regular discussions with the regional data management

community and continues to sponsor the QARTOD effort.

## Classification

### *Executive Order 12866*

Under Executive Order (E.O.) 12866, if the proposed regulations are a “significant regulatory action” as defined in § 3(f) of the Order, an assessment of the potential costs and benefits of the regulatory action must be prepared and submitted to the Office of Management and Budget (OMB). OMB has determined that this action is not a “significant” regulatory action under E.O. 12866.

### *Regulatory Flexibility Act*

Pursuant to section 605 of the Regulatory Flexibility Act (RFA), at the proposed stage, the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities.

During the public comment period for the proposed rule, NOAA received several comments from the IOOS Regional Associations regarding the economic impact of pursuing certification; NOAA did not receive any comment from the Small Business Administration (SBA) on the matter.

The comments NOAA received on the certification included that:

- NOAA is underestimating the time, effort, and expense that it will take to come into full compliance with the proposed regulations and would be a major new burden on the limited resources of the RICE.
- The assumption that the information needed to document compliance with the regulations is already generally available is incorrect. Several of the documents that are requested will need to be assembled and formatted from existing documents.
- The rule might have the unintended consequence of reducing the amount of non-federal data now being made available through the RICE’s regional portals. NOAA responds to the comments as follows:

The Integrated Coastal and Ocean Observation System Act of 2009 (ICOOS Act or Act) directs NOAA to “promulgate program guidelines to certify and integrate non-Federal assets, including regional information coordination entities into the System.” This rule establishes the criteria and procedures for certifying and integrating RICEs into the Integrated Coastal and Ocean Observation System (System), in compliance with the ICOOS Act.

Specifically, the rule requires RICEs to provide NOAA with certain information about their organizational structures, financial capabilities and makeup, oversight, and data quality assurance methods in order to obtain certification under the ICOOS Act. In return for providing NOAA with data of known quality via replicable means and with oversight, NOAA will provide the RICEs with liability protection for activities related to their work on the dissemination and use of observation data. Integration into the System formally establishes the role of the RICE and ensures that the data collected and distributed by the RICE are managed according to the best practices, as identified by NOAA.

Currently, there are eleven RICEs that NOAA expects may be impacted by these regulations, corresponding to those entities that currently coordinate the regional ocean and coastal observing system efforts of the U.S IOOS. RICEs are generally partnerships of entities in the academic, private, governmental, tribal, and non-governmental sectors. Five of the RICEs are organized as not-for-profit organizations under § 501(c)(3) of the Internal Revenue Code; the other six are organized pursuant to Memorandums of Agreement between the constituent members. Most of these eleven RICEs employ from three to five full or part-time individuals, either directly or as contractors. Some or all of these RICEs may be considered “small organizations” under the RFA, although that status is unclear. 5 U.S.C. 601(4).

Regardless of organizing instrument, RICEs primarily depend on funds from NOAA for their operations. Through a series of cooperative agreements, NOAA has been funding these eleven RICEs since FY 2005 to develop the organizational structure, operating procedures, and data management capacity necessary to serve as the entities responsible for planning, coordinating, and operating the regional observing systems. Funding levels to build the organization and coordination capacity of these eleven RICEs, made available through these cooperative agreements, varies by region, but has typically ranged from \$300K to \$400K per year per RICE. In addition, beginning in FY 2008, each of these eleven RICEs entered into cooperative agreements with NOAA to support data collection, data management, and development of products and services. In FY 2012, the funding amounts for these eleven RICEs ranged from \$1.4 million to \$2.5 million per RICE.

This rule establishes generally applicable criteria for data collection and quality that all RICEs must meet, in

order to be incorporated into the System and to obtain the liability protection under the Act. In the proposed rule, NOAA set out the expected time of 293 hours that RICEs may need to comply with these rules and submit their applications for incorporation. The additional documentation requirements will help ensure that all RICE data meets the same minimum standard of quality, and it will help NOAA verify compliance with this rule’s requirements. NOAA acknowledges that undertaking these efforts may result in some significant time outlays by RICEs, in particular because it may require them to create new procedures to document data management practices. However, NOAA does not expect the RICEs will incur significant costs, but would instead re-prioritize existing resources, as a result of this rule, because these efforts will not affect their current funding agreements with NOAA, and much of the work, particularly the data management work, is consistent with their overall work plans established for these agreements.

NOAA will allow RICEs to use other documents they may already possess to demonstrate they meet certification requirements. Thus, NOAA does not expect the other costs associated with organizing and submitting the information required for certification to NOAA will be significant because in the case of the regional associations, this information is similar to what has been developed as part of their NOAA funded work.

Additionally, most RICEs have some data management and quality control procedures in place. NOAA acknowledges that satisfying the certification requirements may result in a RICE having to re-allocate existing funds to implement new data management practices, and to document that required data management practices are in place. NOAA based its hourly burden estimate on the time it would take a RICE, of average maturity, to meet the standards, but expects that some RICEs will expend less time and fewer resources to meet the new requirements. However, since the RICEs have different levels of data management maturity and have applied varied amounts of staff and financial resources towards data management, NOAA cannot determine the exact costs this rule may impose on any given RICE.

Finally, NOAA notes that this rule does not require RICEs to incur these expenses or time to become certified. RICEs may still apply for grants from NOAA, even if they are not certified. Indeed, NOAA expects those RICEs currently receiving NOAA funds under

the ICOOS Act to seek certification, but again, lack of certification does not preclude funding opportunities. NOAA does not intend to create disincentives to participate in the U.S. IOOS, but rather to formally establish the organizational qualities of a RICE to ensure a high uniform level of data collection, management, and distribution practices, which NOAA will certify. Therefore, if a RICE wants to be incorporated into the System, and receive the liability protection from NOAA the Act authorizes, then they will need to be certified which includes ensuring their data collection and management practices meet the standards set out in this rule.

Because this rule does not require RICEs to incur any costs to continue operating, but only if they seek certification and the benefits of liability protection under the ICOOS Act, and because the costs to RICEs that seek certification will vary, NOAA maintains that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, no Regulatory Flexibility Analysis is required, and none has been prepared.

Nonetheless, in response to the comments to the certification under the RFA that NOAA received during the comment period to the propose rule, NOAA has made the following changes to this final rule:

- Revised § 997.15(a) to state that a RICE be given notice of an audit and that the NOAA will coordinate with the RICE on the timing and process for the audit.
- Revised § 997.13(c) to require a RICE only seek approval from NOAA for substantive changes to its organizational structure or Strategic Operational Plan.
- Revised § 997.15(c) to allow a RICE 45 days to request in writing a reconsideration of NOAA's decision to decertify or to notify NOAA of corrective action.
- Revised § 997.23(d)(4)(i) to bound the extent of the requirement to a tangible asset that is functionally complete for its intended purpose and has a capital cost of over \$5000. Revised § 997.23(f)(3) to state that the RICE is not responsible for performing quality control on data it makes available that is accessed from a federal data source.
- Deleted the requirement (proposed as § 997.23(g)(2)) that a RICE describe its plans for diversifying funding sources.

#### **Paperwork Reduction Act**

This rule contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA), which OMB has approved under control number 0648–0672.

It is expected that there will be a total of eleven applicants, corresponding to those entities that currently coordinate the regional ocean and coastal observing system efforts of U.S. IOOS, that will pursue certification as a RICE. The response time for each applicant is estimated to be 290 hours. The burden of effort associated with the collection of information is needed to demonstrate that the necessary policies, standards, data, information, and services to function in the role of a RICE are appropriately established, coordinated, overseen and enforced.

During the public comment period for the proposed rule, NOAA received several comments regarding the estimated amount of effort necessary to develop and submit the information requested to document compliance with the certification requirements. In summary, these comments expressed that NOAA underestimates the time, effort, and expense that it will take to come into full compliance with the proposed regulations and would be a new burden on the limited resources of the RICE. These comments, and NOAA's response, are addressed in the "Response to Comments" section above.

NOAA did not receive any public comments on the application form; however the form was revised to incorporate the changes to the rule requirements. NOAA does not expect that these changes will result in any additional burden on applicants.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

Dated: May 30, 2014.

**Holly A. Bamford,**

*Assistant Administrator for Ocean Services, and Coastal Zone Management.*

#### **List of Subjects in 15 CFR Part 997**

Science and technology, Ocean observing, Certification requirements.

- For the reasons set forth in the preamble, NOAA amends 15 CFR chapter IX by adding subchapter G, consisting of part 997, to read as follows:

#### **Subchapter G—Requirements for Certification by NOAA of Non-Federal Assets Into the Integrated Coastal and Ocean Observation System**

#### **PART 997—REGIONAL INFORMATION COORDINATION ENTITIES**

##### **Subpart A—General**

Sec.

997.1 Definitions.

997.2 Acceptance of procedures by a RICE.

##### **Subpart B—Certification and Decertification Process for a Regional Information Coordination Entity (RICE)**

997.10 Eligibility.

997.11 Application process.

997.12 Review by NOAA.

997.13 Certification process.

997.14 Certification duration and renewal.

997.15 Audit and decertification.

997.16 Final action.

##### **Subpart C—Certification and Application Requirements for a RICE**

997.20 General.

997.21 Organizational structure.

997.22 Membership policy.

997.23 Strategic operational plan.

997.24 Gaps identification.

997.25 Financial oversight.

997.26 Civil liability.

**Authority:** 33 U.S.C. 3603 *et seq.*

##### **Subpart A—General**

###### **§ 997.1 Definitions.**

**Certification.** For purposes of these regulations, the term "certification" means the granting by NOAA of status to a non-federal entity as a participating RICE of the System authorized by section 12304 of the ICOOS Act. An applicant will not be considered to be participating in the System unless 1) it agrees to meet the certification standards issued by the Administrator issued herein, and 2) the Administrator declares the applicant to be part of the System as a certified RICE.

**Equipment.** For purposes of these regulations, the term "equipment" is defined as a tangible asset that is functionally complete for its intended purpose and has a capital cost of over \$5,000. Both individual sensors and collections of sensors on a platform are considered equipment and are subject to the \$5,000 minimum cost.

**Non-Federal assets.** The term "non-Federal assets" means all relevant coastal and ocean observation technologies, related basic and applied technology research and development, and public education and outreach programs that are integrated into the System and are managed through State, regional organizations, universities, nongovernmental organizations, or the private sector.

*Owned and/or operated by the RICE.* The term “owned and/or operated by the RICE” means non-Federal Assets that are either owned and/or operated directly by the RICE, or supported financially in part or in full by the RICE.

*Regional Information Coordination Entity.* The term “regional information coordination entity” means an organizational body that is certified or established by contract or memorandum by the lead Federal agency (NOAA) designated in the ICOOS Act, and that coordinates State, Federal, local, and private interests at a regional level with the responsibility of engaging the private and public sectors in designing, operating, and improving regional coastal and ocean observing systems in order to ensure the provision of data and information that satisfy the needs of user groups from the respective regions. The term “regional information coordination entity” includes regional associations described in the System Plan.

*Employee of a Regional Information Coordination Entity.* The term “Employee of a Regional Information Coordination Entity” means an individual identified in § 997.23(d)(3) or (f)(1) of these Regulations and satisfies the requirements listed in § 997.26(c).

*System.* The term “System” means the National Integrated Coastal and Ocean Observation System established in accordance with section 12304 of the ICOOS Act (33 U.S.C. 3603).

*System Plan.* The term “System Plan” means the plan contained in the document entitled “Ocean.US Publication No. 9, The First Integrated Ocean Observing System (IOOS) Development Plan,” as updated by the Council under these regulations.

#### **§ 997.2 Acceptance of procedures by a RICE.**

By its voluntary entrance or participation in the System, the RICE acknowledges and accepts the procedures and requirements established by these regulations.

### **Subpart B—Certification and Decertification Process for a Regional Information Coordination Entity (RICE)**

#### **§ 997.10 Eligibility.**

Any non-Federal entity may submit an application for certification as a RICE as defined in the ICOOS Act and these Regulations.

#### **§ 997.11 Application process.**

(a) The applicant for certification shall submit an application package containing the information and documentation outlined in subpart C of this part. The submission package shall

include the application form, available online at <http://www.ioos.noaa.gov/certification>.

(b) Submission shall be made to NOAA at the address below, or to such other address as may be indicated in the future: Director U.S. IOOS Program Office, NOAA, 1100 Wayne Ave, Suite 1225, Silver Spring, MD 20910. Submissions may also be made online at <http://www.ioos.noaa.gov/certification>.

#### **§ 997.12 Review by NOAA.**

(a) After receiving an application package, NOAA shall have up to 90 calendar days to review the application package and decide whether to certify the applicant.

(b) Before the 90 calendar days have elapsed, NOAA may request additional information, in which case NOAA shall have up to 30 additional calendar days after that additional information has been received by NOAA, above and beyond the original 90 calendar days, to review the application package and decide whether to certify the applicant.

(c) NOAA’s decision whether to certify the applicant shall be based on whether the RICE demonstrates that it satisfies the current IOOC certification criteria and these regulations.

#### **§ 997.13 Certification process.**

(a) NOAA’s decision whether to certify the applicant, along with the reason for its decision, shall be delivered to the applicant via letter delivered by first class mail and by electronic means.

(b) Applicants receiving a certification determination in the affirmative shall be designated as “certified” RICEs by NOAA. NOAA shall memorialize this status via a memorandum of agreement with the applicant. Certification shall mean that a RICE is incorporated into the System.

(c) A certified RICE shall provide NOAA with written notification of the RICE’s intention to substantively change its organizational structure or Strategic Operational Plan, and shall request approval from NOAA for the change. After receiving the written notification, NOAA shall have up to 30 calendar days to review the requested change and decide whether to approve the requested change. NOAA’s decision, along with the reason for its decision, shall be included in a written notification to the RICE.

#### **§ 997.14 Certification duration and renewal.**

(a) Certification of a RICE shall be for a term of 5 years, unless otherwise specified by the NOAA Administrator.

(b) Certification may be renewed, at the request of the RICE, for a period of

five years. A RICE seeking to renew its certification shall provide NOAA with a written request to renew at least 120 calendar days before the expiration of the existing certification. The request shall include the application form, available online at <http://www.ioos.noaa.gov/certification>, and all information providing evidence that the applicant satisfies the IOOC certification criteria and NOAA regulations promulgated to certify and integrate non-Federal assets into the System.

(c) After receiving a written request for renewal of certification, NOAA shall have up to 90 calendar days to review the request and decide whether to renew the certification.

(d) Before the 90 calendar days have elapsed, NOAA may request additional information, in which case NOAA shall have up to 30 additional calendar days after that additional information has been received by NOAA, above and beyond the original 90 calendar days, to review the request and decide whether to renew the certification.

(e) NOAA’s decision whether to renew the certification shall be based on whether the RICE continues to demonstrate that it satisfies the current IOOC certification criteria and these regulations. NOAA’s decision, along with the reason for its decision, shall be included in a written notification to the RICE.

#### **§ 997.15 Audit and decertification.**

(a) NOAA may audit a RICE that it has certified to ensure compliance with the IOOC certification criteria and these regulations. NOAA will notify the RICE of its intent to conduct an audit and will coordinate with the RICE on the audit schedule and process.

(b) NOAA may decertify a RICE. In general, a RICE may be decertified when:

(1) The results of an audit indicate that the RICE no longer satisfies the requirements under which it was certified; or

(2) Other relevant reasons for decertification become apparent.

(c) NOAA’s intent to decertify a RICE, along with the identification of a specific deficiency(ies) and a recommended corrective action(s), shall be included in a written notification to the RICE. After receiving NOAA’s written notification, a RICE shall have up to 45 calendar days to request in writing that NOAA reconsider its intent to decertify the RICE. The RICE’s request for reconsideration shall contain sufficient information for NOAA to determine whether to grant the request for reconsideration. Alternatively, the RICE may correct the deficiency(ies)

identified by NOAA within 45 calendar days, notify NOAA in writing of the corrective action(s) taken, and provide sufficient evidence for NOAA to determine the correctness and effectiveness of the corrective action(s) taken.

(d) If a RICE submits to NOAA a written request for reconsideration or a written assertion that the identified deficiency(ies) has been corrected, NOAA shall have up to 60 calendar days after receipt of the request or assertion, to review the request for reconsideration or the assertion of corrective action. NOAA's decision, along with the reason for its decision, shall be delivered to the applicant via letter delivered by first class mail and by electronic means.

(e) Upon decertification, a RICE shall no longer be incorporated into the System.

(f) A RICE may act voluntarily to terminate its certification at any time by notifying NOAA in writing of its desire to do so. Upon receipt of the notification by NOAA, the RICE will no longer be incorporated into the System.

#### **§ 997.16 Final action.**

NOAA's decision, whether to certify, renew or decertify a RICE shall be considered final agency action.

### **Subpart C—Certification and Application Requirements for a RICE**

#### **§ 997.20 General.**

(a) For the purposes of these certification regulations, when the verb "describe" is used it indicates that the RICE shall give an account in text that responds to the requirement. This text shall contain sufficient information to demonstrate how the RICE satisfies the certification requirement. The RICE may include a link(s) to additional information. When the verb "document" is used, it indicates that the RICE shall furnish a document(s) that responds to the requirement. A text statement accompanying the document(s) will normally be necessary to provide context for the document(s) and to demonstrate how the RICE satisfies the certification requirement. The RICE may include a link to a document in the accompanying text statement.

(b) Documentation that addresses the certification requirements may include references to existing RICE documents. All documents and materials may be submitted directly to the U.S. IOOS Program Office or made accessible for public viewing on the RICE's Web site.

(c) To become certified, a RICE must submit an application that addresses

each of the requirements listed in this subpart.

#### **§ 997.21 Organizational structure.**

(a) To become certified, a RICE must demonstrate an organizational structure capable of gathering required System observation data, supporting and integrating all aspects of coastal and ocean observing and information programs within a region and that reflects the needs of State and local governments, commercial interests, and other users and beneficiaries of the System and other requirements specified in this subchapter and the System Plan.

(b) The application shall:

(1) Describe the RICE's organizational structure (e.g., 26 U.S.C. 501(c)(3) tax-exempt organization, establishment via MOU or MOA).

(2) Document the RICE's ability to satisfy applicable legal criteria for accepting and disbursing funds, and entering into agreements. Sufficient documentation may be provided in the form of: Evidence of a current grant, cooperative agreement, or contract in good standing with the Federal government; or evidence of fiscal agreements, standard operating procedures for financial activities, and proof of an audit process.

(3) Document the RICE's measures for addressing issues of accountability and liability. For this criterion, accountability and liability refer to the RICE's governance and management activities. Sufficient documentation may be provided in the form of a conflict of interest policy for the Governing Board or governing body, which clearly states that a member of the governing board will declare any conflict of interest he or she may have and will recuse him or herself from associated funding decisions that may result in the Board member or a direct family member benefiting financially, and a policy statement in the RICE's by-laws that addresses liability issues.

(4) Describe the process the RICE uses to set priorities for distributing funds (e.g., requirement for Governing Board or governing body approval when responding to funding opportunities or adjusting to funding level changes in existing agreements); and

(5) Document the by-laws, signed articles of agreement, or any binding agreements that demonstrate how the RICE establishes and maintains a Governing Board or governing body. The documentation shall demonstrate:

(i) How the composition of the Governing Board or governing body is selected and how it is representative of regional ocean observing interests.

NOAA defines "representative" in this specific context to include geographic, sector, expertise, and stakeholder considerations.

(ii) How and with what frequency the RICE solicits and receives advice on RICE participant diversity, stakeholder coordination, and engagement strategies, to ensure the provision of data and information that satisfy the needs of user groups.

(iii) How the RICE collects and assesses user feedback to gauge the effectiveness of the regional system and subsystems in satisfying user needs, and how the RICE responds to this user feedback in setting its priorities.

Sufficient documentation may be provided in the form of a description of the method the RICE uses in its annual planning process to assess priorities among the identified user needs in the region and to respond to those user needs, and

(iv) Steps the RICE takes to ensure decisions on priorities and overall regional system design are transparent and available. At a minimum, RICE priorities and regional system design decisions shall be made accessible for public viewing on the RICE's Web site.

#### **§ 997.22 Membership policy.**

The application shall describe:

(a) The process by which individuals or organizations may formally participate in the governance activities of the RICE;

(b) The rights and responsibilities of this participation;

(c) The process by which the RICE strives for organizational diversity through intra-regional geographic representation, and diversity of activities and interests from both public and private sectors; and

(d) How the RICE allows for participation from adjacent regions or nations.

#### **§ 997.23 Strategic operational plan.**

(a)(1) To become certified, a RICE must:

(i) Develop and operate under a strategic operational plan that will ensure the efficient and effective administration of programs and assets to support daily data observations for integration into the System, pursuant to the standards approved by the Council; and

(ii) Work cooperatively with governmental and non-governmental entities to identify and provide information products of the System for multiple users within the service area of the regional information coordination entities.

(2) The application must contain a Strategic Operational Plan, which is a

high-level document that outlines how a RICE manages and operates an integrated regional observing system. This Plan should evolve as a RICE matures, new technologies become available, regional priorities change, and new users and stakeholders are identified. The Plan may be responsive to changing funding levels, and shall contain sections that each address the requirements in paragraphs (b) through (g) of this section, referencing other plans directly when applicable.

(b) *Background and Context.* The Strategic Operational Plan shall contain a Background and Context section that describes:

(1) The role of the RICE in furthering the development of the regional component of the System;

(2) The process by which the RICE updates the Strategic Operational Plan at least once every five years and how the RICE seeks inputs from the broader user community; and

(3) The RICE's primary partners and any contributing observing systems. For the purposes of § 997.23, NOAA defines a primary partner as any organization or individual that contributes significant staff time, funding or other resources to project activities. This is not an exhaustive list of all RICE partners but the primary partners the RICE is working with on a given project.

(c) *Goals and Objectives.* The Strategic Operational Plan shall contain a Goals and Objective section that describe:

(1) How the RICE addresses marine operations; coastal hazards; ecosystems, fisheries and water quality; and climate variability and change; and

(2) The major objectives that guide the RICE's priorities for data collection and management, development of products and services, research and development, and education and outreach.

(d) *Operational Plan for the Observing System.* The Strategic Operational Plan shall include or reference an Operational Plan for the Observing System that:

(1) Describes the desired outcomes of the observing system;

(2) Describes the elements of the operational integrated observing system that will deliver those outcomes;

(3) Documents to NOAA's satisfaction that the individual(s) responsible for RICE operations has the necessary qualifications and possesses relevant professional education and work experience to deliver observations successfully. At a minimum the Strategic Operational Plan shall:

(i) Identify the individual(s) responsible for overall RICE management;

(ii) Identify, as applicable, the individual(s) responsible for observations system management across the region;

(iii) Provide the curriculum vitae for each identified individual; and

(iv) Identify the procedures used to evaluate the capability of the individual(s) identified in § 997.23(d)(3) to conduct the assigned duties responsibly; and

(4) Describes how the RICE manages ongoing regional system operations and maintenance. At a minimum the Strategic Operational Plan shall:

(i) Describe the RICE's standard operating procedures for calibrating, validating, operating, and maintaining equipment owned and/or operated by the RICE regularly and in accordance with manufacturer guidance or industry best practice. Equipment is defined in § 997.1; and

(ii) Describe the RICE's standard operating procedures for maintaining equipment inventories, shipping logs and instrument history logs for equipment owned and/or operated by the RICE.

(e) *Development of a Strategy to Sustain and Enhance the System.* The Strategic Operational Plan shall describe its strategy for balancing changes in regional priorities with the need to maintain established data sets, the primary value of which may be in their long-term records. At a minimum the description shall:

(1) Identify the guiding principles that inform the strategy;

(2) Reference and show connections to a long-term (five-to-ten-year) regional Build-out Plan for the full implementation of the regional observing system based on the RICE's priorities and identified user needs; and

(3) Relate the annual planning process the RICE uses to review its priorities in light of funding levels and its plans for system enhancement as outlined in the regional Build-out Plan.

(f) *Data Management and Communications (DMAC) Plan.* The Strategic Operational Plan shall include or reference a DMAC Plan that:

(1) Documents to NOAA's satisfaction that the individual(s) responsible for management of data operations for the RICE has the necessary technical skills, and possesses relevant professional education and work experience to support DMAC capabilities and functionality for the System. At a minimum the DMAC Plan shall:

(i) Identify the individual(s) responsible for the coordination and management of observation data across the region;

(ii) Provide the curriculum vitae for the identified individual(s); and

(iii) Identify the procedures used to evaluate the capability of the individual(s) identified in § 997.23(f)(1) to conduct the assigned duties responsibly.

(2) Describes how data are ingested, managed and distributed, including a description of the flow of data through the RICE data assembly center from the source to the public dissemination/access mechanism. The description shall include any transformations or modifications of data along the data flow pathway including, but not limited to, format translations or aggregations of component data streams into an integrated product.

(3) Describes the data quality control procedures that have been applied to data, not obtained through a federal data source, that are distributed by the RICE. All data shall be quality controlled and QARTOD procedures shall be employed for data with QARTOD manuals. For each data stream, describe the quality control procedure applied to the data, by the RICE or other named entity, between the data's collection and publication by the RICE. The description will also include a reference to the procedure used.

(4) Adheres to the NOAA Data Sharing Procedural Directive.<sup>1</sup> The System is an operational system; therefore the RICE should strive to provide as much data as possible, in real-time or near real-time, to support the operation of the System. When data are collected in part or in whole with funds distributed to a RICE through the U.S. IOOS Program Office, the RICE should strive to make the data available as soon as logically feasible for each data stream. When data are not collected with funds distributed to a RICE through the U.S. IOOS Program Office, the data may be made available in accordance with any agreement made with the data provider.

(5) Describes how the RICE will implement data management protocols promulgated by the IOOC and the U.S. IOOS Program Office in a reasonable and timely manner as defined for each protocol; and

(6) Documents the RICE's data archiving process or describes how the RICE intends to archive data at a national archive center (e.g., NODC, NGDC, NCDC) in a manner that follows guidelines outlined by that center. Documentation shall be in the form of

<sup>1</sup> NOAA Data Sharing Policy for Grants and Cooperative Agreements Procedural Directive, Version 2.0 [https://www.nosc.noaa.gov/EDMC/documents/EDMC\\_PD-DSPNG\\_final\\_v2.pdf](https://www.nosc.noaa.gov/EDMC/documents/EDMC_PD-DSPNG_final_v2.pdf).

a Submission Agreement, Submission Information Form (SIF) or other, similar data producer-archive agreement.

(g) *Budget Plan.* The Strategic Operational Plan shall include or reference a Budget Plan that:

- (1) Identifies who supports the RICE financially;
- (2) Identifies how RICE priorities guide funding decisions; and
- (3) Assesses funding constraints and the associated risks to the observing System that the RICE must address for the future.

#### **§ 997.24 Gaps identification.**

(a) To become certified, a RICE must identify gaps in observation coverage needs for capital improvements of Federal assets and non-Federal assets of the System, or other recommendations to assist in the development of annual and long-terms plans and transmit such information to the Interagency Ocean Observing Committee via the Program Office.

(b) The application shall:

(1) Document that the RICE's asset inventory contains up-to-date information. This could be demonstrated by a database or portal accessible for public viewing and capable of producing a regional summary of observing capacity;

(2) Provide a regional Build-out Plan that identifies the regional priorities for products and services, based on its understanding of regional needs, and a description of the integrated system (observations, modeling, data management, product development, outreach, and R&D). The RICE shall review and update the Build-out Plan at least once every five years; and

(3) Document the priority regional gaps in observation coverage needs, as determined by an analysis of the RICE asset inventory and Build-out Plan. The RICE shall review and update the analysis of priority regional gaps in observation coverage needs at least once every five years.

#### **§ 997.25 Financial oversight.**

(a) To become certified, a RICE must comply with all financial oversight requirements established by the Administrator, including requirement relating to audits.

(b) The application shall document compliance with the terms and conditions set forth in 2 CFR Part 215—Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations, Subpart C—Post Award Requirements. Subpart C prescribes standards for financial management

systems, among others. (Compliance with this criterion can be demonstrated by referencing any existing grant, cooperative agreement, or contract the RICE has with NOAA.)

(c) The RICE shall document annually the RICE's operating and maintenance costs for all observing platforms and sensors, etc., owned and/or operated by the RICE. This information shall be made available to NOAA upon request.

#### **§ 997.26 Civil liability.**

(a) For purposes of determining liability arising from the dissemination and use of observation data gathered pursuant to the ICOOS Act and these regulations, any non-Federal asset or regional information coordination entity incorporated into the System by contract, lease, grant, or cooperative agreement that is participating in the System shall be considered to be part of the National Oceanic and Atmospheric Administration. Any employee of such a non-Federal asset or regional information coordination entity, while operating within the scope of his or her employment in carrying out the purposes of this subtitle, with respect to tort liability, is deemed to be an employee of the Federal Government.

(b) The ICOOS Act's grant of civil liability protection (and thus the RICE's limited status as part of NOAA) applies only to a RICE that:

(1) Is participating in the System, meaning the RICE has been certified by NOAA in accordance with the ICOOS Act and these regulations; and

(2) Has been integrated into the System by memorandum of agreement with NOAA.

(c) An "employee" of a regional information coordination entity is an individual who satisfies all of the following requirements:

(1) The individual is employed or contracted by a certified RICE that has been integrated into the System by memorandum of agreement with NOAA, and that is participating in the System, as defined in § 997.26(b);

(2) The individual is identified by the RICE, as required in § 997.23(d)(3) and (f)(1)(i), as one of the individuals responsible for the collection, management, or dissemination of ocean, coastal, and Great Lakes observation data; and

(3) The individual is responsive to federal government control.

(d) The protection afforded to employees of a RICE with regard to liability applies only to specific individuals employed or contracted by a RICE who meet the requirements of § 997.26(c) and who are responsible for the collection, management, or

dissemination of ocean, coastal, and Great Lakes observation data. The RICE must identify to NOAA's satisfaction: The individual(s) responsible for overall system management, as applicable, the individual(s) responsible for observations system management across the region, and the individual(s) responsible for management of data operations across the region. In accepting certification, the RICE will concede to NOAA the power to ensure these individuals comply with the requirements of this rule in their daily operations and that they are responsive to NOAA through the agreement the RICE has with NOAA.

[FR Doc. 2014-13034 Filed 6-4-14; 8:45 am]

**BILLING CODE 3510-JE-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 317**

**[Docket No. FDA-2012-N-1037]**

**RIN 0910-AG92**

#### **Establishing a List of Qualifying Pathogens Under the Food and Drug Administration Safety and Innovation Act**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing a regulation to establish a list of "qualifying pathogens" that have the potential to pose a serious threat to public health. This final rule implements a provision of the Generating Antibiotic Incentives Now (GAIN) title of the Food and Drug Administration Safety and Innovation Act (FDASIA). GAIN is intended to encourage development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections, and provides incentives such as eligibility for designation as a fast-track product and an additional 5 years of exclusivity to be added to certain exclusivity periods. Based on analyses conducted both in the proposed rule and in response to comments to the proposed rule, FDA has determined that the following pathogens comprise the list of "qualifying pathogens:" *Acinetobacter* species, *Aspergillus* species, *Burkholderia cepacia* complex, *Campylobacter* species, *Candida* species, *Clostridium difficile*,