Program Information Notice

Document Number: ONC-REC-PIN-006

Date: September 20, 2011

Document Title: Regional Extension Center Biennial Review Process

TO: Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program Grantees

As stated in the Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program Funding Opportunity Announcement and Grant Application Instructions (FOA), the Office of the National Coordinator for Health Information Technology (ONC) may provide ongoing program guidance to successful award recipients. The purpose of this Program Information Notice (PIN) is to clarify the Regional Extension Center biennial review process as required in section 3012 (c)(8) and (9) of the of the Public Health Services Act:

> "(8) BIENNIAL EVALUATION. — Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive."

> "(9) CONTINUING SUPPORT. — After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services."

Collectively, these two paragraphs constitute the statutory obligation for the Office of the National Coordinator for Health Information Technology (ONC) to conduct a biennial evaluation and to make funding available to successful Regional Extension Centers (RECs) in years three and four of the budget period.

If you have any questions or require further guidance, please contact the Regional Extension Center Division of the Office of Provider Adoption Support at regional-center-applications@hhs.gov.

Sincerely,

/ Farzad Mostashari /

Dr. Farzad Mostashari
National Coordinator for Health Information Technology

Attachment: ONC-REC-PIN-006

I.   PURPOSE

The purpose of this Program Information Notice (PIN) is to clarify the Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program Funding Opportunity Announcement (FOA) and more specifically, clarify the process by which regional extension centers (RECs) will be evaluated through the statutorily required biennial review.

II.   APPLICABILITY

This applies to all RECs that have entered into a cooperative agreement with ONC under the Health Information Technology Extension Program.

III.   BACKGROUND

Section 3012 of the Public Health Services Act (PHSA) provided for health information technology implementation assistance in the form of cooperative agreements for "Regional Extension Centers" (RECs). Successful applicants were eligible for up to four years of funds, but years three and four funding is limited to RECs that obtain an "overall positive" biennial evaluation under section 3012(c)(8) of the PHSA.

ONC interprets "overall positive" to mean successfully meeting or exceeding minimum programmatic milestone thresholds, complying with the objectives listed at section 3012(c)(3), consistently achieving what is documented in Operation Plans (or, where achievement lagged, working diligently with ONC to achieve compliance), successfully submitting all required reports, and in a position reasonably being expected to be fully successful in the objectives if they were afforded two additional years to complete projects. This document establishes the criteria by which an evaluation panel will determine if a REC has met this standard and thus will receive an overall positive biennial evaluation.

The biennial evaluation process will consist of:
- establishing evaluation criteria that can be applied to all RECs in a non-arbitrary and non-capricious manner;
- informing RECs of the standards by which they will be judged, including the data sources that will be used to establish their compliance with the established criteria;
- offering RECs continued assessments and assistance through the REC Program Office and ONC Grants Management Office to keep them informed as to where they stand and offering assistance in methods of achieving successes that will help them to obtain an overall positive evaluation;
- selecting and training panelists to conduct the evaluations in accordance with section 3012 (c)(8) of the PHSA and the applicable Funding Opportunity Announcements (FOA) (EP-HIT-09-003, EP-HIT-09-003-W3, 2010-ONC-REC-S, and 2010-ONC-REC-S-01);
- assess information concerning each REC's performance in order to determine their performance on each criterion and score each REC's overall performance;
- notifying RECs of their evaluation results; and
- providing RECs that materially fail to meet the criteria with their appeal rights.

The panelists will assess each REC's performance against the criteria by reviewing: the REC's original FOA response; milestone performance as collected in the program's Customer Relationship Management (CRM) system, SalesForce.com; compliance with promised performance as reported in quarterly Operations Plans; and compliance with

reporting requirements by reviewing report submission records. These reports and plans are elements of the mandatory reporting obligations under each REC's cooperative agreement.

Criteria for Achieving an Overall Positive Biennial evaluation, per the Authorizing Statute and Funding Opportunity Announcement

A REC is tasked with enhancing and promoting the adoption of health information technology by carrying out certain assigned activities. The Regional Centers are to furnish assistance (defined as education, outreach, and technical assistance) to help providers in their geographic service areas select, successfully implement, and meaningfully use certified EHR technology to improve the quality and value of health care. Regional Extension Centers are also tasked with helping providers achieve, through appropriate available infrastructures, exchange of health information in compliance with applicable statutory and regulatory requirements, and patient preferences. The support that Regional Centers provide must be consistent with any applicable State Plan(s) for health information exchange (HIE) that were developed and HHS-approved under cooperative agreements with ONC under section 3013 of the PHSA, as added by the American Recovery and Reinvestment Act of 2009 (Recovery Act).

As stated in the REC Funding FOAs, the RECs are ultimately expected to achieve three provider-specific milestones:
- Milestone 1: Signed technical assistance contracts between the Regional Center and provider (with receipt of any participation fees required);
- Milestone 2: Documentation of Go-Live status on a certified EHR, with active quality reporting and electronic prescribing;
- Milestone 3: Meeting the meaningful use criteria established by the Secretary. This can be documented either through attestation information from CMS or REC documentation through the SalesForce.com CRM tool.

In response to the ONC FOAs, each REC identified a specific number of providers that it was going to assist in achieving all of the milestones above. Each REC was also required to document all the milestones they achieved using the Salesforce.com CRM tool and submit milestone reports. While ultimately each REC is expected to assist all enrolled providers in their geographic area in reaching the milestones, ONC recognizes that the biennial evaluation represents the halfway point for the program. Thus we need to establish what an overall positive performance would look like at the halfway point of the project. **Therefore, ONC expects that RECs will have recruited the vast majority of their targeted providers, the majority of whom will have implemented an EHR System in accordance with milestone 2 requirements as outlined above. ONC also expects that some of those providers will begin to achieve meaningful use.**

ONC also believes it is reasonable at the halfway point to expect RECs to demonstrate a degree of success in meeting the following goals that were outlined in the scope of service section of the FOAs:
- Education and Outreach to Providers
- National Learning Consortium Participation
- Vendor Selection & Group Purchasing
- Implementation and Project Management
- Practice and Workflow Redesign
- Functional Interoperability and Health Information Exchange
- Privacy and Security
- Progress Towards Meaningful Use
- Local Workforce Support

These goals were meant to help expand on the objectives identified in Section 3012 of the PHSA. They represent many of the types of assistance that a REC will need to provide to ensure that providers can implement, effectively use and maintain health information technology.

Each REC provides quarterly Operations Plans to ONC outlining the specific strategies being used to fulfill commitments to achieving operational goals, initially defined in their funding application. The Operations Plans can therefore be interpreted by professionals with relevant expertise as offering proxies to what a REC would offer if there were a progress reporting requirement for the milestones and operational goals. For example, in measuring a REC's progress in ensuring "Education and Outreach to Providers," one could look at whether the REC has an outreach and marketing plan that properly segments their provider population and identifies specific strategies for recruiting providers. One could then ask whether this approach has helped the REC to recruit PPCPs from the various segments in their region. The Milestone reports and the Operations Plans will therefore serve as data sources for the biennial evaluation.

Each REC has received technical assistance from ONC project officers and grants management specialists since receiving the award to assist them in implementing the work identified in their FOA responses. This technical assistance includes: bi-weekly meetings with project officers to review the status of the work including their Operations Plans and Milestone reports; participation in communities of practice, designed to identify best practices/approaches for addressing the goals identified in the FOA; regional meetings with focused training for staff; on-site visits from project officers and grants management specialists to identify potential implementation barriers and new approaches/tools the REC can provide; monthly REC senior leadership calls to share best practices for program implementation; and senior-level ONC engagement to address specific concerns. The technical assistance was intended to leverage the best practices identified by some RECs and assist RECs in meeting the criteria established by Congress for the biennial review.

IV.   PROCESS

The evaluation will be conducted in three phases, consistent with the three funding cycles used to effectuate the REC awards; see table below.

Grantee Cohort	Beginning of Evaluation & Milestone Cutoff	Operations Plans / Financial Reporting to be Used	Evaluation Completion	Communication of Results	Corrective Action Period
Cycle 1	December 31, 2011	Operations plan 7 (Due 12/31/11)	January 31, 2012	1st week of Feb	60 days, ending April 2012
Cycle 2	February 29, 2012	Operations plan 7*	March 31, 2012	1st week of April	60 days, ending June 2012
Cycle 3	July 31, 2012	Operations plan 9* (Due 7/10/12)	August 31, 2012	1st week of September	60 days, ending November 2012

* RECs will be allowed to submit updated operations plans that reflect additional work completed from the time of the previous submission to the date of the milestone cutoff.

To have access to funding for years three and four, each REC must receive an overall positive evaluation for milestones and operational goals. Assessment and scoring will be conducted by an evaluation panel composed of private experts not affiliated with the REC being evaluated and Federal officials. Panelists will be selected based upon the legislative authority provided for the biennial review and will be given guidance regarding each criterion summarized below. Panelists will then be asked to review each REC's original response to the FOA, its Quarterly Operations Plan and CRM data against the criteria described below.

The evaluation panel will measure the REC's performance against the milestone evaluation criteria and the operational evaluation criteria set forth below, which are, as discussed above, based upon the authorizing statute (PHSA section 3012) and the FOA requirements. This will be done uniformly and through a well-documented process. Panelists will complete the review based on the criteria outlined in this document. RECs that receive the maximum number of points (100) will have met all requirements outlined in its Operations Plan as discussed with ONC project officers.

The reviewers' scores will be collected and each panel will come to consensus on the overall score for each REC. When all scores are collected, they will be normalized. The normalization across all RECs will be used to define the threshold for an overall positive evaluation. A final rank order list of RECs will be submitted to the National Coordinator. Each REC will receive a written summary statement signed by the National Coordinator outlining the outcome of the review. At the completion of the review, an REC will receive notification that it has received either:
1. An overall positive review, with no material findings; or
2. A review that identified material failures that must be addressed immediately through a corrective action plan.

RECs that receive reviews identifying material failures that need to be addressed will have 60 days to do so. These RECs will receive specific objectives that must be achieved in order for the program to receive an overall positive review. Programs that receive an overall positive review, either through the initial review or by achieving the objectives of its corrective action plan, will be allowed to access years three and four funding as identified in their approved budgets. Programs identified as having material failure(s) and fail to meet the objectives of their corrective action plan will be defunded through a process which complies with 45 CFR section 74.90. An appeal may then be requested in accordance with 45 CFR 7462(b) under Part 16 of 45 CFR (Procedures of the Departmental Grant Appeals Board).

Section 1: Milestone Evaluation Criteria

PHSA Reference, §3012 (c)(4)[1]	Funding Opportunity Announcement (FOA) Reference[2]		Evaluation Element & Formula	Threshold	Points / Weight	Scoring
(4) Regional Assistance. – Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following: (A) Public or not-for-profit hospitals or critical access hospitals. (B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act). (C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural). (D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.	*FOA Section II, 2 (p.14):* The key provider-specific milestones include: 1. Signed technical assistance contracts between the Regional Center and provider (with receipt of any participation fees required); 2. Documentation of Go-Live status on a certified EHR, with active quality reporting and electronic prescribing; 3. Meeting the meaningful use criteria established by the Secretary. *Section II, 3 (p.15) :* This assessment will place significant emphasis on the proportion of priority primary-care providers receiving direct technical assistance that were able to achieve successful adoption and meaningful use of certified EHR systems.	1	Milestone 1: # of PPCPs enrolled and documented in CRM / individual REC PPCP target	Using formula at left, percentage equal to or greater than 80%	20	RECs would receive one point for each percentage point above 80% percent. If an REC has met/exceeded their recruitment goal, they would receive 20 points.
		2	Milestone 2: # of PPCPs with documented Go-Live status on a certified EHR, documented in CRM, with active quality reporting and eRx / individual REC PPCP target	Using formula at left, percentage equal to or greater than 35%	10	RECs would receive a half point (0.5) for each percentage point above 35%. If a REC assisted 55% or more of their providers to Milestone 2 they would receive 10 points.
		3	Milestone 3: # of PPCPs achieving MU and documented in CRM / individual REC PPCP target	Using formula at left, percentage equal to or greater than 1%	5	RECs would receive a point for each percentage point at or above 1%. If a REC was able to assist 5% or higher of their providers to Milestone 3 they would receive 5 points.

Scoring: Evaluation Elements 1, 2 and 3 will be scored individually and the REC would receive a composite Milestone score out of a possible 35 total points.

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[1] Public Health Service Act (PHSA) as added by the American Recovery and Reinvestment Act of 2009 (Recovery Act or ARRA)

[2] Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program Funding Opportunity Announcements EP-HIT-09-003, EP-HIT-09-003-W3

Section 2: Operational Evaluation Criteria

PHSA Reference, §3012 (c)(3)	FOA Reference	Evaluation Element	Criteria	Points / Weight	Scoring
A. assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide	*FOA Section I, 2 (p.9-12), Scope of Services –* **Practice and Workflow Redesign** - Regional Centers must provide support for practice and workflow redesign necessary to achieve meaningful use of EHRs. **Implementation and Project Management** - Regional Centers must provide end-to-end project management support over the entire EHR implementation process. **Progress Towards Meaningful Use** – The Regional Centers' personnel shall participate in program training and be able to provide their clients effective assistance in attaining meaningful use.	**Operations Plan**: Including Service Area, Providers and Patients, Org Chart, Vendors and Sub-recipients, Key Activities and Risk Mitigation data, and CAH / RH data as applicable.	PHSA §3012 (c)(3)(A)	10	Objective reviewers will review REC Operations Plans, including Service Area, Providers and Patients, Org Chart, Vendors and Sub-recipients, Key Activities and Risk Mitigation data, and CAH / RH data as applicable. The objective reviewers will keep in mind the purpose of the REC program, defined in the FOA, which states that "The ultimate measure of a Regional Center's effectiveness will be whether it has assisted providers in becoming meaningful users of certified EHR technology." Objective reviewers will assign a score out of 10 points; taking into consideration how the REC has met this element, and adapted its strategy over the first two program years to address new issues, such as the Affordable Care Act (ACA), which may have impacted the market.

Note: The "Evaluation Element" column contains the number "4" aligned with the Operations Plan description.

PHSA Reference, §3012 (c)(3)	FOA Reference	Evaluation Element	Criteria	Points / Weight	Scoring
B. broad participation of individuals from industry, universities, and State governments	*FOA Section V. Criteria 4 (p.33) –* Support from multiple independent stakeholders (e.g., health plans, hospital systems, medical/professional societies and other provider organizations, institutions of higher education, federally recognized state primary care and rural health association(s), quality improvement organization(s), or public health agencies). *Section II. 3. (p.15)* ONC will work with each Regional Center in a collaborative way to develop and implement activities, including multi-stakeholder partnerships that will deliver efficient and effective outreach, education and, technical assistance to the providers in the region the Regional Center serves. Recipients will be required to track progress by collecting specific, standardized data about their Regional Centers' activities and progress toward milestones.	**Operations Plan**: Stakeholder data; including Organizations and Level of Stakeholder Support and CAH / RH data as applicable.	PHSA §3012 (c)(3)(B)	10	Objective reviewers will review REC Operations Plans Stakeholder data; including Organizations and Level of Stakeholder Support data, and CAH / RH data as applicable. The objective reviewers will keep in mind the REC cooperative agreement roles and responsibilities, which are identified as "Recipients are required to collaborate with critical stakeholders listed in this Funding Opportunity Announcement and the ONC team and ONC supported initiatives, including but not limited to, cooperative agreements under section 3013 of the PHSA as added by ARRA" (FOA VI.1.b.). This includes documented collaboration with State HIE(s), State HIT Coordinator(s), Medicaid EHR program(s), and Beacon programs (where applicable). Objective reviewers will assign a score out of 10 points; taking into consideration how the REC has met this element, and adapted their strategy over the first two program years to address new issues, such as the Affordable Care Act (ACA), which may have impacted their market.

Note: The "5" in the Evaluation Element / Criteria area appears to the left, aligned vertically in the middle of the row.

PHSA Reference, §3012 (c)(3)	FOA Reference	Evaluation Element	Criteria	Points / Weight	Scoring
C. active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information	*FOA Section I, 2 (p.9-12), Scope of Services –* **National Learning Consortium -** The Regional Centers will become, upon award, members of a consortium that will be facilitated by the HITRC. All Regional Centers will be required to participate in the consortium and its activities **Vendor Selection & Group Purchasing** - This includes assistance in assessing the health IT needs of priority primary-care providers, and selecting and negotiating contracts with vendors **Privacy and Security Best Practices –** Regional Centers will support providers in implementing best practices with respect to the privacy and security of personal health information	**Operations Plan**: Including Org Chart, Vendors and Sub-recipients, Key Activities and Risk Mitigation data; including Practice & Workflow Design, Implementation Support, Privacy & Security sections 6	PHSA §3012 (c)(3)(C)	10	Objective reviewers will review REC Operations Plans Org Chart, Vendors and Sub-recipients, Key Activities and Risk Mitigation data; including Practice & Workflow Design, Implementation Support, Privacy & Security sections. The objective reviewers will keep in mind that participating in the National Learning Consortium was a key element in all of the FOAs. ONC has provided a wide assortment of technical assistance through the National Learning Consortium, designed to support the RECs in assisting providers. REC participation in these efforts is critical to ensure tools are useful and appropriate. Objective reviewers will assign a score out of 10 points; taking into consideration how the REC have met this element, and adapted their strategy over the first two program years to address new issues, such as the Affordable Care Act (ACA), which may have impacted the market.
D. participation, to the extent practicable, in health information exchanges	*FOA Section I, 2 (p.12) –* **Functional Interoperability and Health Information Exchange –** Regional Centers will assist priority primary-care providers in connecting to available health information exchange infrastructure(s), including local health information exchange organizations and state-based shared utilities or directory services in compliance with applicable statutory and regulatory requirements, patient preferences, and the State Plans for health information exchange (HIE) developed and HHS-approved under cooperative agreements issued by ONC pursuant to Section 3013 of the PHSA as added by the Recovery Act.	**Operations Plan**: Key Activities and Risk Mitigation data; including Interoperability and HIE section 7	PHSA §3012 (c)(3)(D)	10	Objective reviewers will review REC Operations Plans Key Activities and Risk Mitigation data; including the Interoperability and HIE section. The objective reviewers will consider the REC's reported availability of HIE, barriers encountered and resolution described to ultimately support participation in HIEs in their region. Objective reviewers will assign a score out of 10 points; taking into consideration how the REC has met this element, and adapted their strategy over the first two program years.

PHSA Reference, §3012 (c)(3)	FOA Reference	Evaluation Element	Criteria	Points / Weight	Scoring
E. utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department	*FOA Section I, 2 (p.13)* – The Regional Centers will be expected to leverage and undertake activities that are in synergy with, where locally available, the expertise, capability, and activities of practice networks supported by HHS and other federal agencies, including, but not restricted to the Indian Health Service (IHS), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Veterans Affairs (VA), the Department of Defense (DOD), and relevant CMS demonstration projects. *FOA Section IV. 5(p.28)* Coordination with other federal programs, and with related Recovery Act funded activities – how the Regional Centers will utilize, where locally available, the expertise and capabilities of practice networks supported by other federal agencies, such as IHS, HRSA, VA, CMS, and DOD. *CAH/RH Supplemental FOA[3] Section IV, 2 (p.8), Application Submission Information* – Applicants are encouraged to partner with relevant associations and other organizations that have in-depth knowledge of CAHs and Rural Hospital health information technology needs.	**Operations Plan**: Stakeholders data; including Organizations and Level of Stakeholder Support	PHSA §3012 (c)(3)(E)	8 ... 10	Objective reviewers will review REC Operations Plans stakeholder data; including Organizations and Level of Stakeholder Support data, and CAH / RH data as applicable. The objective reviewers will keep in mind the REC cooperative agreement roles and responsibilities, which are identified as "Recipients are required to collaborate with critical stakeholders listed in this Funding Opportunity Announcement and the ONC team and ONC supported initiatives, including but not limited to, cooperative agreements under section 3013 of the PHSA as added by ARRA" (FOA VI.1.b.). This includes documented collaboration with State HIE(s), State HIT Coordinator(s), Medicaid EHR program(s), Beacon programs (where applicable), and organizations that have in-depth knowledge of CAH/RH health information technology needs (for programs awarded Critical Access / Rural Hospital supplemental funds). Objective reviewers will assign a score out of 10 points; taking into consideration how the REC has met this element, and adapted their strategy over the first two program years to address new issues, such as the Affordable Care Act (ACA), which may have impacted the market.

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[3] Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program Funding Opportunity Announcements 2010-ONC-REC-S, and 2010-ONC-REC-S-01

PHSA Reference, §3012 (c)(3)	FOA Reference	Evaluation Element	Criteria	Points / Weight	Scoring
F. integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information	*FOA Section I, 2 (p.12)* – **Local Workforce Support** – The Regional Centers will be expected to partner with local resources, such as community colleges, to promote integration of health IT into the initial and ongoing training of health professionals and supporting staff.	**Operations Plan**: Key Activities and Risk Mitigation data; including Meaningful Use and Workforce sections	PHSA §3012 (c)(3)(F)	10	Objective reviewers will review REC Operations Plans stakeholder data; including Organizations and Level of Stakeholder Support, Key Activities and Risk Mitigation data; including Meaningful Use and Workforce sections. The objective reviewers will keep in mind the REC cooperative agreement roles and responsibilities, which are identified as "Recipients are required to collaborate with critical stakeholders listed in this Funding Opportunity Announcement and the ONC team and ONC supported initiatives, including but not limited to, cooperative agreements under section 3013 of the PHSA as added by ARRA" (FOA VI.1.b.) Objective reviewers will assign a score out of 10 points; taking into consideration how the REC has met this element, and adapted their strategy over the first two program years to address new issues, such as the Accountable Care Act (ACA), which may have impacted the market.

The "9" in the Evaluation Element column appears to the left, aligned between Operations Plan rows.

Statutory Reference	FOA Reference	Evaluation Element		Criteria	Points / Weight	Scoring
Timely Reporting: 45 CFR 74.50; 74.51; 74.52; Recovery Act §1512	*FOA Section VI – Reporting (p. 38) –* Reporting – Recipients are required to comply with all reporting requirements outlined in this Funding Opportunity Announcement and the terms and conditions of the cooperative agreement to ensure the timely release of funds.	10	Quarterly Performance Reports (Operations Plans); Quarterly ARRA Reports; Quarterly Cash Transaction Reports; Annual Financial Status Reports	100% submission	5	RECs will receive a quarter point (0.25) for submission of: - Quarterly operations plans (Total of 7) - Quarterly ARRA Reports (Total of 8) - Response to ONC annual capstone report (Total 1) RECs will receive a quarter point (0.25) for submission of: - OMB Circular A133 Audit (Total of 2) - SF269 (Total of 2)

Scoring: Evaluation Elements 4, 5, 6, 7, 8, 9 and 10 will be scored individually and the REC would receive a composite Operational score out of a possible 65 total points.