

# GUIDE T O THE PROGRESS REPORT P ROCESS:

**DEMONSTR A T ING IMPROVEMENTS AND COMPLI ANCE**

### The ISMA expects organizations found to be in non-compliance with Criteria 1-13 or with relevant accreditation policies to demonstrate compliance through the progress report process. Descriptions of the specific performance issues that must be addressed in the progress report are provided in the decision report recently received from the ISMA. Non-compliance findings in Commendation Criteria 16-38 should NOT be addressed in the progress report.

**Contents of a Progress Report**

For the specific performance issues described for non-compliance findings, providers must:

* describe improvements and their implementation; and,
* provide evidence of performance-in-practice to demonstrate compliance.

The *Reporting Requirements for ISMA Accreditation Criteria/Policies* are presented on pages 2-5 of the *Guide to the Progress Report Process*. This information should be considered in the context of, and limited to, the specific performance issue(s) identified in the recent ISMA decision report.

[***NOTE:*** *If a non-compliance finding is based on a specific type of activity, evidence must be presented that demonstrates improvements in that activity type (e.g., enduring materials, RSS, Internet CME, etc.).*]

**Expectations of Materials Submitted**

All the materials submitted to the ISMA in any format must not contain any untrue statements, must not omit any necessary material facts, must not be misleading, must fairly present the organization, and must be the property of the organization. Materials submitted for accreditation (progress report, evidence of performance-in-practice, other materials) must not include individually identifiable health information, in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

## Decision-Making

Providers will receive a decision from the ISMA based on a review of all of the information and materials submitted as part of the progress report. A progress report review will result in the following feedback from the ISMA:

* **All Criteria in Compliance:** The provider demonstrated that it has corrected the criteria or policies that were found to be in non-compliance.
* **All Criteria Not Yet in Compliance:** The provider has not yet demonstrated that it has corrected all of the criteria or policies that were found to be in non-compliance.

If all criteria or policies that were found to be in non-compliance are not corrected, the ISMA may require another progress report, a focused interview, and/or a change of status may result.

There may be circumstances when the ISMA requires clarification at the time of the provider’s next review to be certain the provider is in compliance, or when a progress report is deferred to a future cohort, because, for example, a provider has not had sufficient time within the context of its CME program to implement improvements or to produce evidence to support compliance.

## Reporting Requirements for ISMA Accreditation Criteria/Policies

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| **The information below provides a guide for determining the structure and content of the Progress Report to address non-compliance findings in Criteria 1-13 and/or the accreditation policies. Responses should be developed in the context of the specific performance issue(s) identified in the decision report recently received from the ISMA.****Please contact ISMA staff if you have questions about what to include in your Progress Report.**  |
| **Mission:** **Expected Results****(former C1)** | **Attach** your CME mission statement **with** the expected results of the program articulated in terms of changes in competence, performance, or patient outcomes. |
| **Program Analysis****(former C12)** | Based on your organization’s review of information and data gathered on changes in learners’ competence or performance or patient outcomes, **describe** your program-based analysis explaining the degree to which you have achieved your CME mission through the conduct of your CME activities/interventions. |
| **Program Improvements****(former C13)** | **Describe** the needed or desired changes you identified, planned, and implemented, as a result of your program-based analysis, that are required to improve on the ability to meet your CME mission. |
| **Educational Needs****(former C2)** | **Provide a description and evidence** from the selected activities to demonstrate:1. That you identify the professional practice gap(s) of your own learners;
2. That you identify the educational needs of your learners that underlie the professional practice gap(s) that you have identified.

As evidence from each activity, state the professional practice gap of the learners and educational need that you determined was the cause of the gap. |
| **Designed to Change****(former C3)** | **Provide a description and evidence** from the selected activities to demonstrate that you generate activities designed to change physician competence, performance, or patient outcomes.As evidence from each activity, state what the activity was designed to change in terms of the learners’ competence or performance or patient outcomes. |
| **Appropriate Formats****(former C5)** | **Provide a description and evidence** from the selected activities to demonstrate that you choose educational format(s) that are appropriate for the setting, objectives, and desired results of the activity.As evidence for each activity, explain why the educational format chose was appropriate for the activity. |

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| **Competencies****(former C6)** | **Provide a description and evidence** from the selected activities to demonstrate that you develop activities in the context of desirable physician attributes (e.g., IOM Competencies, ACGME Competencies). |
| **Analyzes Change****(former C11)** | From the selected CME activities, **provide the data or information generated** about changes in learners’ competence or performance or patient outcomes upon which you based your program-level analysis of changes in learners.Provide **your analysis of changes in learners’** competence, performance, or patient outcomes achieved as a result of your overall program’s activities/educational interventions. |
| **Standard 1:****Ensure Content is Valid****(former C10 and Content Validation Policy)** | **Describe** how you ensure that the content of your CME activities and your accredited CME program meet all four elements of Standard 1 in both the planning and monitoring stages. 1. All recommendations must be based on current science, evidence and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
2. All research referred to, reported, or used in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
3. Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topis, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence and clinical reasoning.
4. Organizations must not advocate for unscientific approaches to diagnosis or therapy, or education that promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.
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| **Standard 2:****Prevent** **Commercial****Bias and** **Marketing in Accredited CE****(former C7-SCS1 and C10)** | **Provide a description and evidence** from the selected activities to demonstrate how you ensured that the content of the accredited activities meet the following expectations:1. The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.
2. Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.

3. The accredited provider must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner. |
| **Standard 3:****Identify, Mitigate and Disclose Relevant Financial Relationships****(former** **C7-SCS 1, 2 & 6)** | **Provide a description and evidence** from the selected activities to demonstrate that you met all elements of Standard 3 in the planning stages.1. Collection Information: Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education.
2. Exclude owners or employees of ineligible companies: Review the information about financial relationships to identify individuals who are owners or employees of ineligible companies. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education.

 3. Identify relevant financial relationships: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.4. Mitigate relevant financial relationships: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.5. Disclose all relevant financial relationships to learners: Disclosure to learners must include each of the following:a. The names of the individuals with relevant financial relationships.b. The names of the ineligible companies with which they have relationships.c. The nature of the relationships.d. A statement that all relevant financial relationships have been mitigated.6. Identify ineligible companies by their name only. Disclosure to learners must not include ineligible companies’ corporate or product logos, trade names, or product group messages.7. Disclose absence of relevant financial relationships. Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies.8. Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education. |

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|  | **Provide a description and evidence** from the selected activities to demonstrate:1. That everyone in a position to control educational content (e.g., faculty, planners, reviewers, and others who controlled content) has disclosed to your organization relevant financial relationships with commercial interests.

For each activity selected, **attach:*** + The form, tool, or mechanism used to identify relevant financial relationships of all individuals in control of content.
	+ A list of all individuals in control of content, specifying their role(s), for example, planner, faculty, content reviewer, etc. in the activity, the name of the ISMA/ACCME-defined commercial interest with which the individual has a relevant financial relationship (or if the individual has no relevant financial relationship), and the nature of that relationship.
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|  | **Provide a description and evidence** from the selected activities to demonstrate:1. That your organization identifies all conflicts of interest prior to an activity.
2. That your organization implements mechanism(s) to resolve all conflicts of interest prior to an activity.

For each activity selected, **attach:*** + A list of all individuals in control of content, specifying their role(s), for example, planner, faculty, content reviewer, etc. in the activity, the name of the ISMA/ACCME-defined commercial interest with which the individual has a relevant financial relationship (or if the individual has no relevant financial relationship), and the nature of that relationship.
	+ Evidence that you implemented your mechanism(s) to resolve conflicts of interest for all individuals in control of content prior to the start of the activity.
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|  | **Provide a description and evidence** from the selected activities to demonstrate:1. That disclosure of all relevant (or no) financial relationships was made to learners prior to the beginning of the activity;For each activity selected, **attach:*** A list of all individuals in control of content, specifying their role(s), for example, planner, faculty, content reviewer, etc. in the activity, the name of the ISMA/ACCME-defined commercial interest with which the individual has a relevant financial relationship (or if the individual has no relevant financial relationship), and the nature of that relationship.
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|  | **Provide a description and evidence** from the selected activities to demonstrate:1. That disclosure of all sources of commercial support, including “in-kind” support, was made to learners prior to the activity. (C7 SCS 6.3-6.5)For each activity selected, **attach:*** A list of commercial supporters by name of company and $ value of any monetary commercial support and/or indicate in-kind support.
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| **Standard 4:****Manage Commercial Support Appropriately** | **Describe** your process(es) for the receipt and disbursement of commercial support (both funds and in-kind support). For each activity selected – if applicable – **attach** 1) a list of all commercial supporters and evidence to demonstrate that the terms, conditions, and purposes of all commercial support are documented in a signed written agreement with the commercial supporter that includes the provider and its educational partner(s) and 2) an income and expense statement, including the receipt and expenditure of commercial support, or indicate, “We did not accept commercial support for this activity.” (SCS 3.13) |
| **Standard 5:****Manage****Ancillary Activities** | 1. Do you organize ***commercial exhibits*** in association with any of your CME activities?

If yes, **describe** how your organization ensures that arrangements for commercial exhibits do not 1) influence planning or interfere with the presentation and 2) are not a condition of the provision of commercial support for CME activities. (SCS 4.1)1. Do you arrange for ***advertisements*** in association with any of your CME activities?

If yes, **describe** how your organization ensures that advertisements or other product- promotion materials are kept separate from the education. In your description, distinguish between your processes related to advertisements and/or product promotion in each of the following types of CME activities: 1) print materials, 2) computer-based materials, 3) audio and video recordings, and 4) face-to-face. (SCS 4.2, 4.4) |
| **Accreditation Statement** | For each activity selected, **attach** evidence from the selected activities to demonstrate that the appropriate accreditation statement was used. |
| **Physician Participation** | **Describe** the mechanism your organization uses to record and verify physician participation for six years from the date of your CME activities. Include one example that demonstrates your practice to record and verify physician participation. |
| **Activity Documentation** | **Describe** the mechanism(s) your organization uses to ensure the retention of activity records/files for the current accreditation term or for the last twelve months, whichever is longer. |

## Format Requirements and Submission Instructions

Make all required submissions according to the ISMA’s specifications and by established deadlines. Failure to do so may result in a delay in consideration of your progress report and/or a change of your organization’s accreditation status. **Your submission must include:**

1. a narrative cover document describing improvements made in specific areas of non-compliance; and,
2. evidence of performance-in-practice for each activity selected, if applicable.
	* Address only those criteria or policies found to be in non-compliance at the time of your last review and only the specific performance issues cited for those criteria or policies in your last decision report. [***NOTE****: Do NOT address non-compliance findings in Commendation Criteria 16-38*]
	* If the activity sample does not offer your organization an opportunity to present evidence that reflects the improvements you have implemented to ensure and demonstrate compliance, please contact the ISMA to discuss possible options in the sampling process.
	* Do NOT use original documents, because the materials will not be returned.

### Instructions for Submitting in Electronic Format

1. Include narrative cover document and evidence of performance-in-practice saved as a single, paginated and bookmarked PDF file. The file you create should appear as a single document when opened. Do not use the Acrobat option to make a PDF “portfolio” style file.
2. Include, in your PDF file, a cover page for each activity selected that specifies:

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| * Full name of your organization
 | * Activity type, as submitted in PARS
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| * Activity title, as submitted in PARS
 | * Directly or jointly provided
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| * Activity date and location, as submitted in PARS
 | * Commercial support was/was not accepted
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1. Create the following bookmarks for the submitted document:
	1. narrative
	2. each activity selected for performance-in-practice review, if applicable,
	3. separate the evidence within each activity and identify it by the criterion or policy to which it pertains.
2. Email the PDF file as an attachment to cstearley@ismanet.org, or if too large, arrange to upload to ISMA’s OneDrive share-file system.

*Please contact Cheryl Stearley, CME Accreditation and Recognition Administrator, by phone at*

*317-454-7731 or by email at* *cstearley@ismanet.org* *if you have any questions about the Progress Report review process.*