



# GUIDE TO THE PROGRESS REPORT PROCESS: DEMONSTRATING IMPROVEMENTS AND COMPLIANCE

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 Criteria 16-22 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

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.

C1	<b>Attach</b> your CME mission statement <b>with</b> the expected results of the program articulated in terms of changes in competence, performance, or patient outcomes.
C2	Provide a description and evidence from the selected activities to demonstrate: <ol style="list-style-type: none"> <li>1. That you identify the professional practice gap(s) of your own learners;</li> <li>2. That you identify the educational needs of your learners that underlie the professional practice gap(s) that you have identified.</li> </ol> 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.
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. <p>As evidence from each activity, state what the activity was designed to change in terms of the learners' competence or performance or patient outcomes.</p>
C4	This criterion has been eliminated effective February 2014.
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. <p>As evidence for each activity, explain why the educational format chose was appropriate for the activity.</p>
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).
C7 (SCS 1)	<p>If your organization has included employees or owners of ISMA/ACCME-defined commercial interests in the planning, development or presentation of CME activities*, please:</p> <ol style="list-style-type: none"> <li>1. Provide a description and evidence from the selected activities of the factors you consider in determining an appropriate role for an ISMA/ACCME-defined commercial interest employee in planning and/or presenting accredited CME; and</li> <li>2. Provide a description and evidence, from the selected activities <u>or other activities</u>, of the mechanisms implemented to ensure that you, as provider, retain complete control of the CME content.</li> </ol> <p>*The use of employees or owners of ISMA/ACCME-defined commercial interests as faculty and planners or in other roles where they are in a position to control the content of accredited CME is prohibited, except in 3 special-use cases where employees/owners of ACCME-defined commercial interests <i>can</i> have a specific, limited role in accredited CME activities. In each instance, the expectations of ISMA/ACCME Accreditation Requirements, including the Standards for Commercial Support, must be met.</p> <ol style="list-style-type: none"> <li>1. Employees/owners of ISMA/ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer/company.</li> <li>2. Employees/owners of ISMA/ACCME-defined commercial interests can control the content of accredited CME activities when the content of the accredited CME activity is limited to basic science research (e.g., pre-clinical research, drug discovery) or the <i>processes methodologies</i> of research, themselves unrelated to a specific disease or compound / drug. In these circumstances, the accredited provider must demonstrate that it has implemented processes to ensure employees of ISMA/ACCME-defined commercial interests have no control of CME activity content that is related to clinical applications of the research/discovery or clinical recommendations concerning the business lines or products of their employer /company.</li> </ol>

	<p>3. Employees / owners of ISMA/ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices. In this circumstance, the accredited provider must demonstrate that it implements processes to ensure that employees of ISMA/ACCME-defined commercial interests have no control of CME activity content that is related to clinical recommendations concerning the business lines or products of their employer/company.</p>
<p><b>C7</b> <b>(SCS 2.1)</b></p>	<p>Provide a description and evidence from the selected activities to demonstrate:</p> <ol style="list-style-type: none"> <li>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.</li> </ol> <p>For each activity selected, <b>attach</b>:</p> <ul style="list-style-type: none"> <li>• The form, tool, or mechanism used to identify relevant financial relationships of all individuals in control of content.</li> <li>• 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.</li> </ul>
<p><b>C7</b> <b>(SCS 2.3)</b></p>	<p>Provide a description and evidence from the selected activities to demonstrate:</p> <ol style="list-style-type: none"> <li>1. That your organization identifies all conflicts of interest prior to an activity.</li> <li>2. That your organization implements mechanism(s) to resolve all conflicts of interest prior to an activity.</li> </ol> <p>For each activity selected, <b>attach</b>:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<p><b>C7</b> <b>(SCS 6.1, 6.2, 6.5)</b></p>	<p>Provide a description and evidence from the selected activities to demonstrate:</p> <ol style="list-style-type: none"> <li>1. That disclosure of all relevant (or no) financial relationships was made to learners prior to the beginning of the activity;</li> </ol> <p>For each activity selected, <b>attach</b>:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>
<p><b>C7</b> <b>(SCS 6.3, 6.4,6.5)</b></p>	<p>Provide a description and evidence from the selected activities to demonstrate:</p> <ol style="list-style-type: none"> <li>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)</li> </ol> <p>For each activity selected, <b>attach</b>:</p> <ul style="list-style-type: none"> <li>• A list of commercial supporters by name of company and \$ value of any monetary commercial support and/or indicate in-kind support.</li> </ul>
<p><b>C8</b> <b>(SCS 3)</b></p>	<p>Describe your process(es) for the receipt and disbursement of commercial support (both funds and in-kind support). For each activity selected – if applicable – <b>attach</b> 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)</p>

<b>C8 (SCS 3.7-3.8)</b>	<b>Attach</b> your written policies and procedures governing honoraria and reimbursement of expenses for planners, teachers, and/or authors.
<b>C9 (SCS 4)</b>	<ol style="list-style-type: none"> <li>Do you organize <b>commercial exhibits</b> in association with any of your CME activities? If yes, <b>describe</b> 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)</li> <li>Do you arrange for <b>advertisements</b> in association with any of your CME activities? If yes, <b>describe</b> 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)</li> </ol>
<b>10 (SCS 5)</b>	<p><b>Describe</b> the planning and monitoring your organization uses to ensure that:</p> <ol style="list-style-type: none"> <li>The content of CME activities does not promote the proprietary interests of any commercial interests. (C10 SCS 5.1) (i.e., there is not commercial bias)</li> <li>CME activities give a balanced view of therapeutic options. (C10 SCS 5.2)</li> </ol>
<b>ISMA's Policy on Content Validation</b>	<p><b>Describe</b> the planning and monitoring your organization uses to ensure that:</p> <ol style="list-style-type: none"> <li>The content of CME activities is in compliance with the ISMA's content validity value statements.* (Policy on Content Validation)</li> </ol> <p>*ISMA's Policy on Content Validation: All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis. Providers are not eligible for ISMA accreditation or reaccreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients.</p>
<b>C11</b>	<ol style="list-style-type: none"> <li>From the selected CME activities: Provide the <b>data or information generated about changes in learners'</b> competence <u>or</u> performance <u>or</u> patient outcomes upon which you based your program-level analysis of changes in learners.</li> <li>Provide <b>your analysis of changes in learners'</b> competence, performance, or patient outcomes achieved as a result of your <u>overall</u> program's activities/educational interventions.</li> </ol>
<b>C12</b>	Based on your organization's review of information and data gathered on changes in learners' competence or performance or patient outcomes, provide your program-based analysis explaining the degree to which you have achieved your CME mission through the conduct of your CME activities/interventions.
<b>C13</b>	<b>Describe</b> 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.
<b>C14</b>	This criterion has been eliminated effective February 2014
<b>C15</b>	This criterion has been eliminated effective February 2014
<b>Accreditation Statement</b>	For each activity selected, <b>attach</b> evidence from the selected activities to demonstrate that the appropriate accreditation statement was used.
<b>Physician Participation</b>	<b>Describe</b> 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.
<b>Activity Documentation</b>	<b>Describe</b> 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:**

- a) a narrative cover document describing improvements made in specific areas of non-compliance; and,
- b) 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 Criteria 16-22**]
  - 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 Hard Copy

- a) Include narrative cover document and evidence of performance-in-practice. Evidence for each activity selected should be submitted in an 8 ½ X 11" file folder. Do not submit evidence in binders. Separate the evidence within each activity and identify it by the criterion or policy to which it pertains. Separation can be achieved with cover pages, for example.
- b) Affix a label to the front of each file folder that specifies:

• Full name of your organization	• Activity type, as submitted in PARS
• Activity title, as submitted in PARS	• Directly or jointly provided
• Activity date and location, as submitted in PARS	• Commercial support was/was not accepted

- c) Submit a duplicate set of all materials, including cover letter/narrative and performance-in-practice file folders by the specified deadline to: **ISMA, 322 Canal Walk, Indianapolis, IN 46202**

### Instructions for Submitting in Electronic Format

- a) Save narrative cover document and evidence of performance-in-practice 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.
- b) Include, in your PDF file, a cover page for each activity selected that specifies:

• Full name of your organization	• Activity type, as submitted in PARS
• Activity title, as submitted in PARS	• Directly or jointly provided
• Activity date and location, as submitted in PARS	• Commercial support was/was not accepted

- c) 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.
- d) Email the PDF file as an attachment to: [cstearley@ismanet.org](mailto:cstearley@ismanet.org)

Please contact Cheryl Stearley by phone at 317-454-7731 or by email at [cstearley@ismanet.org](mailto:cstearley@ismanet.org) if you have any questions about the progress report review process.