



Use Of A Risk Stratification Tool (RST) to Prospectively Assess Potential for Commercial Influence on CME

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None of the authors have anything to disclose in relation to the content of this presentation



Objectives

- Define risk stratification
- Apply principles of risk stratification to CME
- Discuss elements of CME activities that confer risk for noncompliance with the Standards For Commercial Support
- Apply a risk stratification tool to a sample group of activities
- Discuss targeted interventions to manage high risk activities



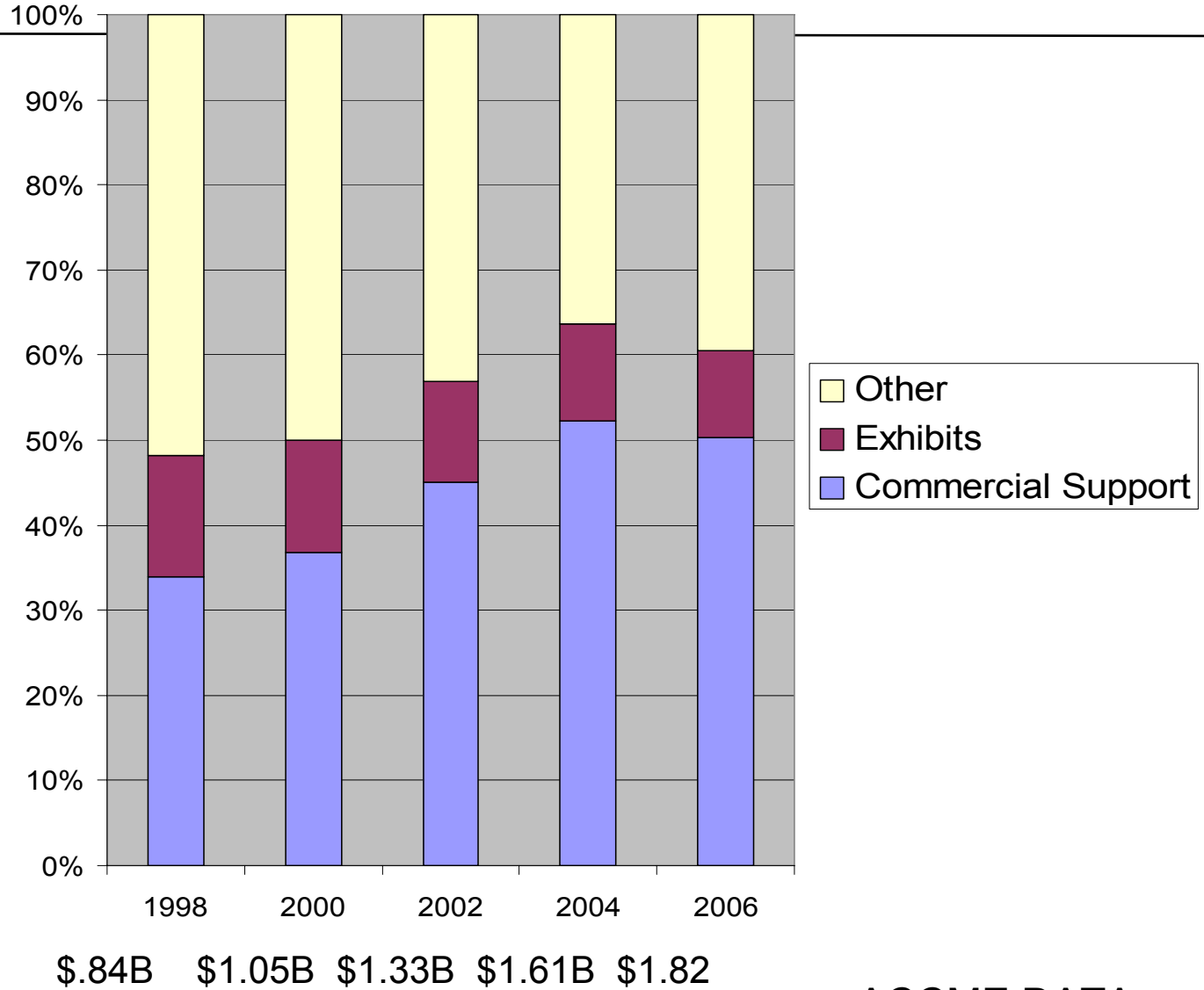
Agenda

- Introduction 10 min
- Large Group Case Study 5 min
- Risk Stratification Tool 15 min
- Small Group Exercise 30 min
- Large Group Report Out 15 min



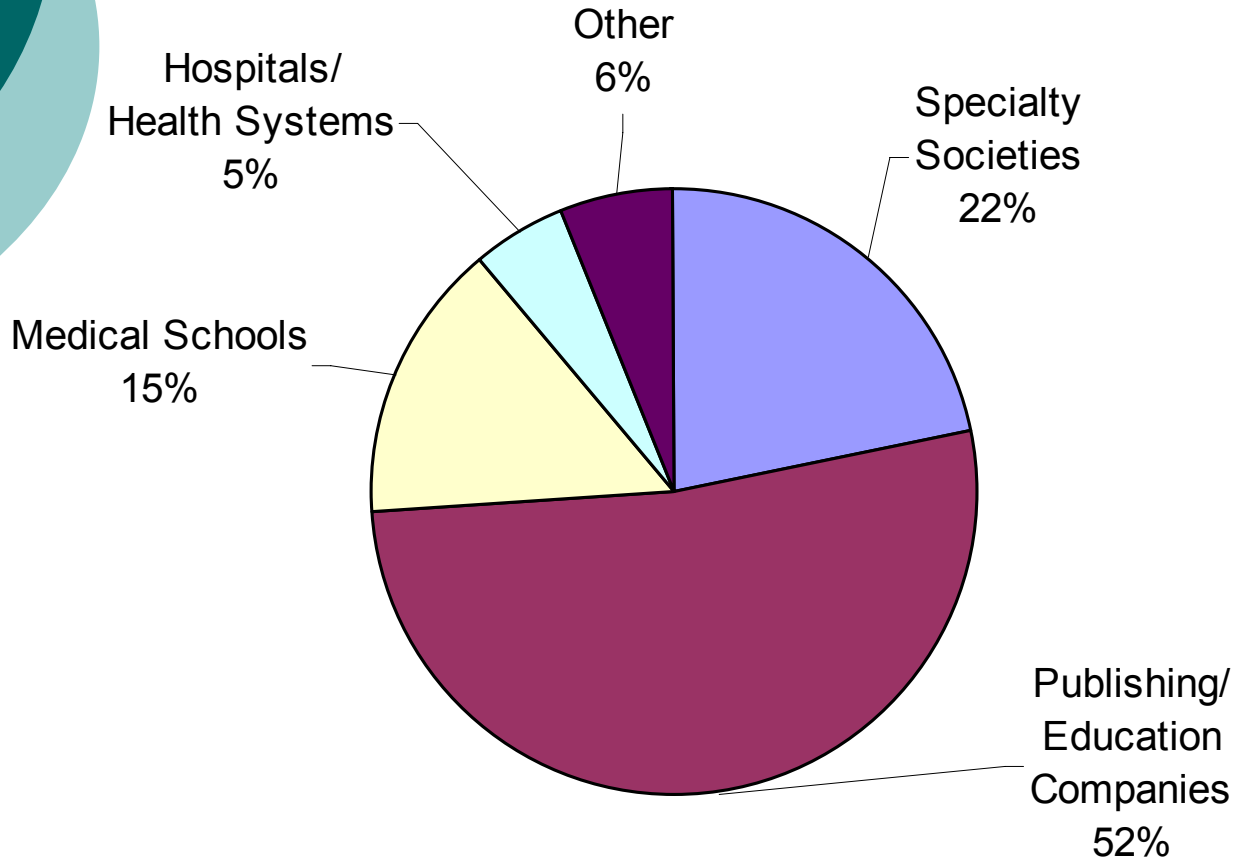
The Current Environment

Increasing Levels of Commercial Support



ACCME DATA

Commercial Support by Provider Type



Specialty societies receive 75% of the advertising/exhibit revenue



Concerns About Commercial Support

- Can industry-sponsored CME activities be balanced and unbiased?
- Does industry support drive the overall agenda for CME?
- Do CME providers and learners have the capability to manage and identify commercial bias?
- Does industry support for CME erode public trust?



The Response

- Position papers
 - Macy Foundation Report
 - AAMC Task Force on Industry Funding of Medical Education
 - AMA Ethical Opinion Draft
- Regulatory responses
 - Senate Finance Committee



The Response

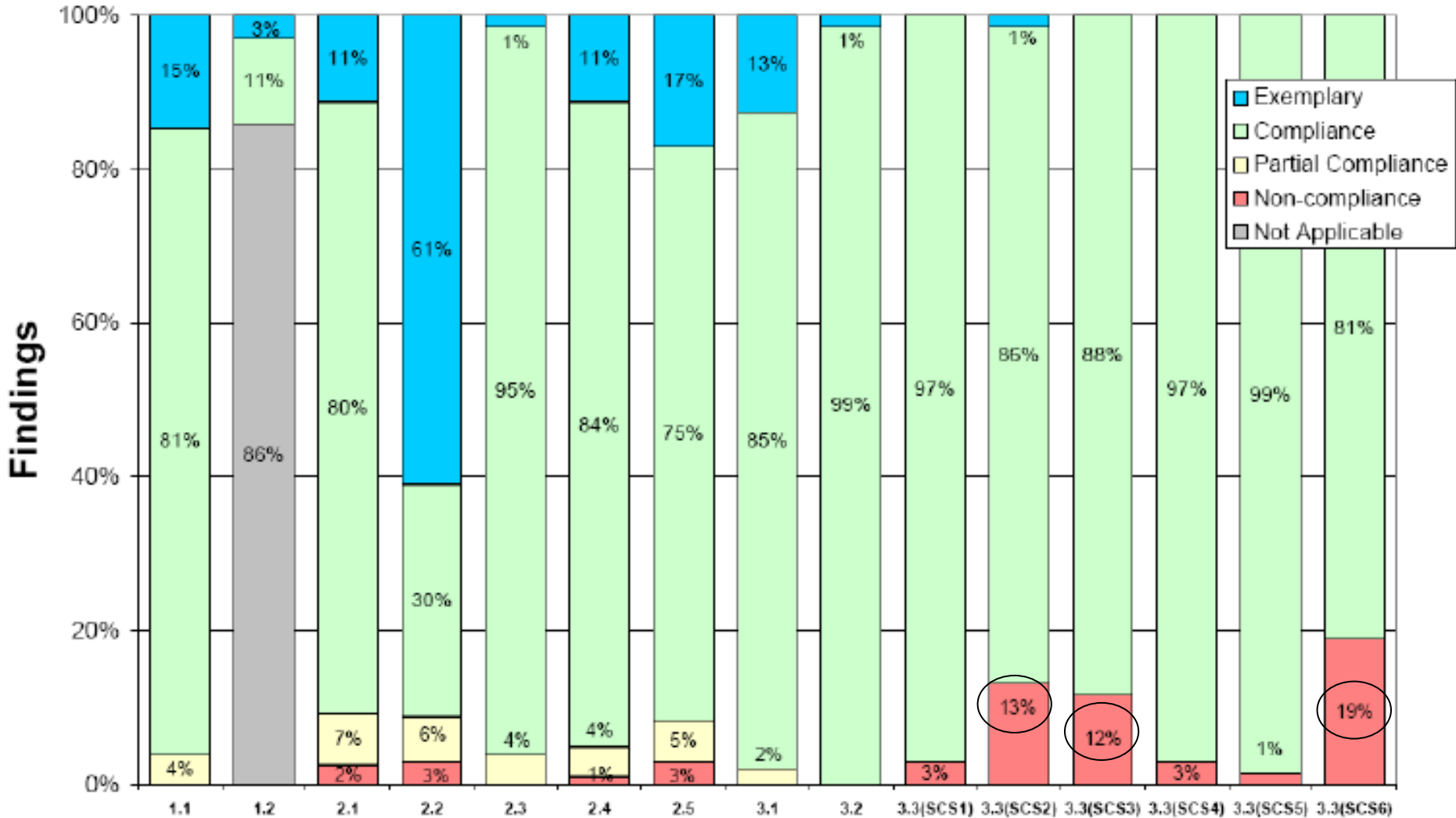
- ACCME position
 - Response to Senate Comm.
 - “Bridge to Quality”
 - Implementing New Criteria
- Academic Medical Centers
 - Policies on institutional COI



Challenges to CME Providers

- Producing quality, unbiased, scientifically rigorous education
- Complying w/ Standards and Guidelines
- Funding CME with ↓ institutional dollars
- Managing COI of 1° content developers
- Managing COI of institutions
- Appropriately using resources and people
- Managing change

Table 10: Summary of Compliance with the Essential Areas and Elements (2006)





Case Study: Broncho-Endoscopy

- Based on your experience as a CME professional, what “risk category” would you assign to this case?
 - Very high risk
 - High risk
 - Moderate risk
 - Low risk



What is Risk Stratification?

- A statistical process to determine detectable characteristics associated with an increased chance of experiencing unwanted outcomes.^[i]
- By identifying factors before the occurrence of an event, it is possible to develop targeted interventions to mitigate their impact.

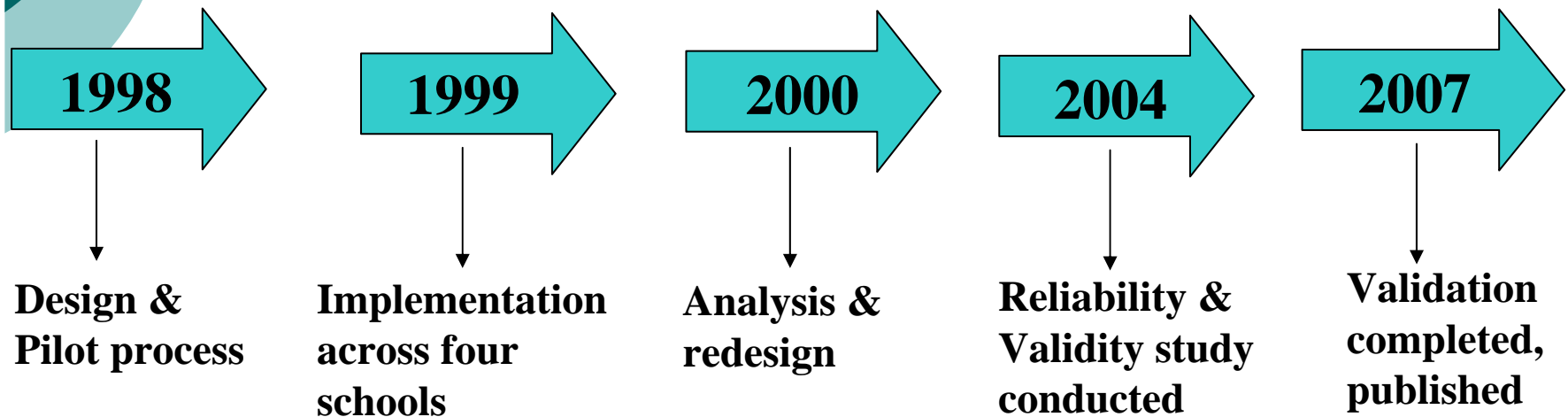
[i] Miller CC, Reardon MJ, Safi HJ. Risk stratification: A practical guide for clinicians. Cambridge University Press, Cambridge, UK. 2001.



Risk Stratification Allows Providers to Identify, Quantify and Modify Risk

- Identify issues that increase risk for
 - injecting bias in the educational content
 - non-compliance with accreditation standards
 - endangering accreditation status
- Aid providers in decisions about whether and/or how to certify a “risky” program
- Stimulate providers to apply strategies to assure that compliance is achieved

Risk Stratification Tool (RST) has Been Analyzed and Validated



Barnes BE., Cole JG., Thomas-King, C., Zukowski R., Allgier-Baker T., Rubio DM., Thorndyke LE. A Risk Stratification Tool to Assess Commercial Influences on Continuing Education. *J Contin Educ Health Prof.* 2007;27(4):234-240.

CACME RISK STRATIFICATION
January, 2002

ISSUE		SCORE
1. Joint or co-sponsorship		
No		0
Yes		
	Joint or co-sponsor is non-profit organization	1
	Joint or co-sponsor is a for-profit organization	2
2. Experience with joint sponsor		
	Positive experience (in compliance with Essentials and SCS and CME office's policies and procedures)	-1
	Not applicable	0
	No experience	1
	Negative (not in compliance with Essentials, SCS, or CME office's policies and procedures)	3
3. Same live curriculum repeated on multiple occasions in a commercially supported activity (includes live internet activity or teleconference)		
	No	0
	Yes	3
4. Involvement by an entity outside of the CME office in logistical activities (marketing, conference management, enduring material development, etc.)		
	Handled entirely by the CME office	0
	Some or all of logistical functions delegated by the CME office to one or more entities (including joint or co-sponsor)	1
	Some or all of logistical functions delegated by a joint or co-sponsor to one or more entities	2
	Some or all of logistical functions delegated by the CME office or joint or co-sponsor to an entity engaged by a commercial supporter	3
5. Experience with entity external to the CME office responsible for logistics		
	Positive (in compliance with Essentials and SCS and CME office's policies and procedures)	-1
	Not applicable	0
	No experience	1
	Negative experience (not in compliance with Essentials or SCS or CME office's policies and procedures)	3
6. Responsibility for funds management (receipt of commercial funds, processing of tuition revenue, payment of expenses, etc.)		
	Handled entirely by the CME office	0
	Some or all aspects handled by a not-for-profit entity outside of the CME office (including another department within the accredited institution)	2
	Some or all aspects handled by a for-profit entity external to the CME office	3

7. Level of involvement of any of the commercial supporters or their agent(s) (risk score is additive but cannot exceed 3)		
	Educational grant only	0
	Site selection	1
	Marketing	1
	Target audience selection	1
	Topic recommendation	1
	Speaker recommendation	1
8. Number of commercial supporters		
	None	0
	2 or more	2
	1, prior good experience (all commercial supporters in compliance with Essentials, SCS, and CME office's policies and procedures)	3
	1, no prior experience	4
	1, bad prior experience (one or more commercial supporters not in compliance with Essentials, SCS, or CME office's policies and procedures)	5
9. The primary intent of the activity involves the discussion of experimental or off-label uses		
	No	0
	Yes	2
10. Amount of commercial support as a % of anticipated total revenue		
	None	0
	Up to 50% of revenue will be commercial support	1
	51% - 99% of revenue will be commercial support	3
	100% of revenue will be commercial support	4
11. Amount of exhibit support as a % of anticipated total revenue		
	None	0
	Up to 50% of revenue will be exhibit revenues	1
	51% - 99% of revenue will be exhibit revenues	2
	100% of revenue will be exhibit revenue	3
12. Presence of a relationship between course director and commercial supporter that might affect the scientific balance of the activity		
	No	0
	Yes	2

TOTAL _____

Low risk: ≤ 2
Moderate risk: 3 to 11
High risk: 12 to 19
Very high risk: ≥ 20



Risk is Affected by Commercial Support and Degree of Delegation

- Elements of Risk Stratification Tool
 - Primary control vs. delegation of functions
 - Involvement of for-profit organizations
 - Potential reach of activity
 - Previous experience with partners
 - Nature and degree of conflict of interest
 - Nature and degree of commercial support



The RST Predicts Risk: Prospectively and Objectively

- Provides rationale for allocating resources to activities at highest risk for non-compliance
- Higher risk activities require greater direct involvement of CE office in planning, monitoring and evaluation
- Lower risk activities may have responsibilities delegated



Risk Category Drives Decisions

- Whether to certify the activity
- Oversight plan for ensuring compliance
- Selection of methods for monitoring
- High risk activities → greater CE resources
- Lower risk activities → fewer CE resources
- High/Very high risk → higher review levels
- Supports a variable CE management fee



CE Office Develops a Management Plan

- Multi-level COI Management Plan
- Involvement of Dean for CME
- CME committee or advisory board
- Degree of delegation by CE office
- Independent academic review
- Mandatory on-site monitoring
- Multiple methods of evaluation



Large Group Exercise

Broncho-Endoscopy *Revisited*

- Review the case again
- Use the Risk Stratification Tool to score and assign a risk category to the case

- Did you get the same answer?



Small Group Exercise

Applying the Risk Stratification Tool

- Break into small groups of 4-6
- Score each case individually
- Discuss each case
 - What category of risk is present?
 - Where are the major risks?
 - Would you proceed?
 - What management plan would you develop to manage the risk?



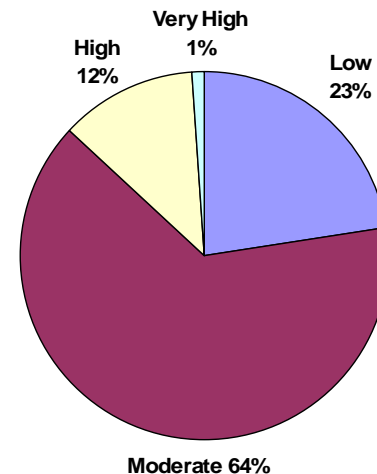
Large Group Discussion

- Was there agreement within your group with risk category assignment?
- Was the RST a useful instrument in the process?
- How did the risk category affect the management plans for each case?
- How would the RST be useful in your office?

Use the RST for Individual Activity Assessment and Program Evaluation

- Prospective - Allows appropriate distribution & balance of CE office resources
- Retrospective - Allows profile of overall CE program
- Useful in training staff
- High risk activities are not inherently “bad” or “off limits”

CACME Overall Risk Category (FY04)





Conclusions

- The RST delineates elements that place activities at risk for non-compliance with SCS
- Prospective assessment of risk can aid in:
 - Appropriate activity management
 - CE program overall profile
 - Allocation of CE office resources
 - Compliance with standards and regulations



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Thank you!

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