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Office of the Secretary
Public Company Accounting Oversight Board
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Eli Lilly and Company (Lilly) appreciates the opportunity to provide its views on the Public Company Accounting Oversight Board's ("PCAOB") proposed auditing standard, *An Audit of Internal Control over Financial Reporting That Is Integrated with an Audit of Financial Statements*. Lilly supports the PCAOB's continued willingness to solicit input and address various concerns of preparers and auditors on the important topic of internal control reporting. We have long supported the position that effective internal controls are vital to the integrity of the financial reporting process.

We believe passage of the Act has helped to restore investor confidence in the financial reporting and disclosure practices of larger companies. We agree that the proposed guidance has the potential to assist companies in achieving a better balance of benefits and costs while still achieving the legislative intent of the Act, consistent with the PCAOB's intent. We appreciate the thought and effort put into developing the standards. We also appreciate the fact that the PCAOB has listened to comments expressed at the two Roundtables and in other forums about the balance between costs and benefits of Sarbanes-Oxley compliance. The new standards open the door for productive dialogue with our auditors about how to make our assessments and their audits more efficient. We especially appreciate that the proposed standards have moved to a more principles-based approach. This allows for a high level of judgment in applying the principles to individual company situations, moving away from the one-size-fits-all approach that many companies and their auditors have been following.

Our primary concern is that auditors will need to be assured that the PCAOB inspection practices will align with the proposed standards. Otherwise, auditors will be reluctant to change their approach until after an inspection cycle, which can be more than a year from the time of the audit. If the intent of the inspections is to drive improvements in the auditors' approach, adherence to the proposed standards and greater consistency among the firms, then the feedback must be provided on a timely basis.

Top-down, risk-based approach
We believe that the primary driver of efficiency will be the focus on a top-down, risk-assessed approach. The focus on key critical controls that would detect a material misstatement, rather than a significant deficiency, creates the possibility that companies can significantly reduce the

number of key controls to be assessed. This reduction will allow for a lower assessment effort overall and more attention and focus on the critical controls, which should increase the likelihood that any existing material weakness would be discovered and remediated.

The auditor is directed to focus on the same significant accounts as for the financial statement audit and the relevant assertions, based upon an assessment of risk. After determining major classes of transactions and significant processes, the auditor focuses on control activities in those processes that address the risk of misstatement to each relevant assertion for each significant account. A reduction in the controls tested will improve both efficiency and quality.

The proposed standards also suggest that risk assessments drive several audit decisions, in each case limiting the extent of audit work. The identification of significant accounts to include in scope is based upon an assessment of the risk of potential material misstatement in the account. Relevant assertions are also chosen based upon a risk assessment, asking the question of "what could go wrong" with in-scope accounts. Once key controls are identified, the risk of the control not operating effectively is assessed to determine the nature and extent of testing evidence to be obtained. For companies with multiple locations, the changes in the multi-location guidance shift from an emphasis on coverage to an emphasis on identifying and including locations based on risk. At each decision point, the application of thoughtful risk assessments should reduce and focus the audit effort, as compared to the effort expended under the current standard.

Alignment between management and auditors

In the absence of management guidance, companies have had to follow AS2 to satisfy the requirements of the auditors. With the flexibility to focus on a top-down, risk-based approach to detect only material weaknesses, we expect to narrow our focus and align the level of testing with the level of risk assessed in the significant accounts and related processes, achieving a better tradeoff between the quality of controls assurance and the cost of compliance.

We want to emphasize how critical it is that the audit standards are aligned with the SEC's management guidance. The auditors must be comfortable with management's assessment approach to optimize reliance and achieve overall cost savings. And although the requirement for an opinion on management's assessment process has been eliminated, the opinion on the controls themselves remains. As currently written, the proposed standard will not allow management to make as significant of changes as the management guidance if management wants to continue or even expand the level of reliance on it's testing by the external auditors. In fact, we have heard from our external auditors that the proposed standards have caught up to their audit approach and expect minimal changes. A more detailed or conservative approach on the part of the auditors will drive the companies to continue to document and assess lower-risk controls, thereby continuing to incur unnecessary costs and failing to achieve the objective of more effective and efficient assessments.

Auditors have understandable concerns about the impact of PCAOB inspections, since the inspection reports issued to date have not focused on the risk of over-auditing. Some auditors seem to be taking a wait-and-see approach, anticipating guidance from the firms' national

offices. Their hesitation to embrace the idea of big change is perhaps understandable. Barriers to change for the auditors could manifest themselves in individual engagement teams being unwilling to make changes without support from the firm's national office, in national office guidance that interprets the standards more restrictively than intended, and/or in firms collaborating to create de facto guidance that reverts to more prescriptive language and mutes the positive changes in the proposed standards.

Removal of opinion on management's assessment

We support the elimination of the opinion on management's assessment process. However, we do not expect to see substantial efficiencies result from the change since the auditor still needs to obtain an understanding of management's process as a starting point to understanding the company's internal control, assessing risk and determining the extent to which he or she will use the work of others. If companies want to optimize auditor reliance on management testing, they will still need to align with the auditors' standards of testing and documentation.

Company-level controls

Companies have put much thought and effort into identifying and enhancing company-level controls. Although we are confident that company-level controls are the key to preventing future Enron-type failures, we still struggle to get full credit for these controls in reducing testing of transaction level controls, particularly indirect company-level controls such as ethics programs and Board of Director oversight. Paragraphs 16 and 17 of the proposed standard indicate that a top down approach begins with company-level controls, that those controls must be tested, and that the evaluation could result in increasing or decreasing other auditor testing. This language does not express a strong conviction that company-level controls can have a significant effect on the extent of other testing. We ask that the PCAOB reconsider whether the language could be enhanced to more strongly support giving credit for strong company-level controls.

Leveraging company-level controls to reduce other testing has been more successful in the case of direct company-level controls, such as analytic reviews and budget-to-actual comparisons. One issue here has been establishing the precision at which these controls operate. With the new focus on detecting material misstatements, the precision should be less of an issue. In paragraph 43 the proposed standard states that some company-level controls might adequately prevent or detect misstatements to one or more relevant assertions. We would like to see the word "material" inserted before "misstatements" twice in this paragraph to emphasize that the acceptable level of precision is higher than in the past.

One other note is that the proposed standards use the term "company-level controls" to describe direct and indirect controls other than process level controls. The SEC guidance uses the term "entity-level controls" in a similar way. Aligning the terms between the two documents could help eliminate some of the confusion that already exists about the definitions.

Focus on changes in controls

The proposed standards encourage the use of prior knowledge and audit results to guide the risk assessment and testing approach. The standards clearly allow for reducing the required evidence in subsequent years based upon the type and results of prior years' testing and the

extent of changes in the controls. Also, the proposed standards explicitly provide for benchmarking of automated controls. Using prior year knowledge and results will allow for additional reductions in audit effort.

As helpful as we expect that guidance to be, we would like to see the proposed standards explicitly provide auditors the flexibility to focus on only **changes** in controls. This would mean changing the expectation that each year's audit stands on its own and allow for benchmarking or rotation of testing controls in areas in addition to automated controls. If the auditor could confirm that the control design had not changed and that the control had been operating effectively in past audits, the auditor should have the freedom to forgo any testing of that control, particularly for lower risk controls. Also, the auditors could limit the scope of their walkthroughs to only the changes.

Reliance by auditors on the work of others
The second proposed standard expands the potential for auditor reliance on the work of others, which should further reduce the costs of external audits and better align the audit and the management assessment. The proposed standard defines guidelines for competence and objectivity that could expand reliance on work by company employees and contractors other than internal audit. It removes the "principal evidence" requirement and also removes the requirement for original work in testing of controls in the control environment. We believe that these changes will be effective in facilitating greater reliance and lower costs. We support the separate statement allowing reliance upon a broader group of individuals determined to be competent and objective for testing internal controls.

In addition in paragraph 40, it suggests the auditor should either perform the walkthroughs himself or herself or supervise the work of others who provide direct assistance. We draw a major distinction between supervise versus direct the work of others. We believe the term supervise is interpreted by the auditors too stringently and would involve extensive work by the auditors when they have already determined the individuals to be competent and objective. For example, we would suggest the auditors be allowed to direct the work of others performing walkthroughs on behalf of the auditors through guidance and oversight but not require detailed supervision of all their activities.

Multiple-location changes
We believe that the shift from a quantitative approach to a risk-based approach will allow companies to vary testing in locations based more on risk than on coverage and will certainly improve efficiency, significantly in some cases.

Deficiency evaluation
The change in the likelihood component of the material weakness and significant deficiency definitions from "more than remote" to "reasonable possibility" should reduce the time spent on evaluating deficiencies. The change in the magnitude component of the significant deficiency definition from "more than inconsequential" to "significant" should raise the threshold for significant deficiencies and also allow for increased judgment in determining significant deficiencies.

Detection of Fraud

The proposed standard states in paragraph 45 that, along with other assertions, auditors should address controls that mitigate the risk of material misstatement due to fraud. This clarification is somewhat helpful as it has been unclear whether companies and auditors should be identifying and assessing controls that would detect ANY fraud committed by a senior executive. Contradicting that point, however, is the language in paragraph 79 which says that fraud of any magnitude on the part of senior management is an indicator of a material weakness. It may be more appropriate to remove that statement from paragraph 79 and include a statement about senior management fraud in paragraph 78, which discusses deficiencies that would ordinarily result in at least significant deficiencies. We recognize the strong sentiments and sensitivity around the detection of fraud; however, we draw a major distinction between insignificant expense report exceptions compared to an intentional manipulation of financial statements. It may also be appropriate to define the specific types of fraud that should be considered to be an indicator of a material weakness (i.e. management fraud – senior management intentional manipulation of financial statements, versus employee fraud – inappropriate expense reporting). Also, the definition of senior management seems fairly broad. Adding the term "senior" to the last sentence in the Note on the top of Page A1-30 of the Standard would make the definition more consistent.

With all the buzz about auditors focusing more on fraud, it would be helpful if the proposed standard provided more guidance on what is expected of the auditor rather than allowing them to be more conservative in this area as opposed to the risk assessment focus for the audit of internal control over financial reporting to identify material misstatements. We would not support periodic forensic auditing to detect material misstatements due to fraud.

Wording of the Audit Opinion

The unqualified opinion example in paragraph 96 still includes the language, "We also have audited management's assessment", even though the last sentence of the sample opinion says that "Our responsibility is to express….an opinion on the company's internal control over financial reporting based on our audits." And the final opinion paragraph states, "Also in our opinion, W Company maintained, in all material respects, effective internal control over financial reporting…." With the elimination of the requirement for a separate opinion on management's assessment process, the above language in the introductory paragraph of the opinion is potentially misleading or confusing, even in light of the fact that the direct audit of the internal controls gives indirect assurance about management's assessment process.

We believe that the language should be changed to indicate that the auditors are auditing the internal controls themselves, not management's assessment of the controls. Or alternatively, to continue to address the requirement of Section 404(b) of the Sarbanes-Oxley Act of 2002 that the auditors attest to, and report on, the assessment made by the management of the issuer, the language could be changed to state explicitly that the auditors have audited management's assessment by performing a direct audit of the internal controls.

The audit of management's assessment is also referenced in paragraph 1 of the proposed standard, and we suggest that language should also be changed to remove the words "of management's assessment" in that paragraph.

Scaling the Audit for Smaller Companies
We agree the proposed standard has allowed the auditor to use more judgment through the top-down, risk-based approach. This should also allow the auditor to tailor his/her approach to plan and perform the audit based on risk and complexity of the organization. We do not believe it is necessary to call out the scalability under a separate heading within the proposed standard and suggest no distinction be drawn between the accelerated filer and non-accelerated filer. This information and guidance clearly falls under the role of risk assessment. In addition, we would suggest footnote 6 to the proposed standard be eliminated.

Effective date
We hope that we have clearly communicated our strong support for the proposed standards. So that we can realize the expected benefits in the near future, we suggest that the proposed standards and the proposed guidance should be implemented as soon as possible. For the benefit of calendar year companies the effective date should be as early as possible in calendar 2007. To minimize disruption and inefficiency, the proposed standards need to be effective before design evaluations begin for calendar year companies, which would typically begin in the second quarter.

Thank you for considering our views. We would be happy to discuss our comments and recommendations at your convenience.

Sincerely,

Arnold C. Hanish
Executive Director and Chief Accounting Officer
Eli Lilly and Company