
Phone 317 276 2000

September 14, 2006

Nancy M. Morris, Secretary
Securities & Exchange Commission
100 F Street, N.E.
Washington, DC 20549-1090

Reference: File Number S7-11-06

Dear Ms. Morris:

Eli Lilly and Company (Lilly) appreciates the opportunity to provide its views on the U.S. Securities and Exchange Commission's ("Commission") *Concept Release Concerning Management's Reports on Internal Control over Financial Reporting*. Lilly supports the Commission'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, but we also believe there is opportunity for additional improvements in compliance practices that will better balance benefits and costs while still achieving the legislative intent of the Act, specifically Section 404 on internal control reporting. These improvements include additional Commission interpretive guidance for management with concurrent changes to the Public Company Accounting Oversight Board's ("PCAOB") Auditing Standard No. 2 ("AS2").

Lilly believes additional interpretive guidance in the form of broad concepts and principles would facilitate a principles-based approach thereby allowing desired flexibility and judgment while minimizing the potential for unintended consequences requiring change or rework to existing processes. We believe the changes to AS2 must be concurrent with guidance issued by the Commission in order to realize the desired changes. Any inconsistencies in the final guidance and AS2 would likely increase costs and introduce new inefficiencies.

The Commission should consider that if new overly prescriptive guidance is issued and sufficient management judgment and flexibility is limited or restricted, the value of risk-based assessing of internal control over financial reporting could be lost and there could be a potential to lose credibility with the public investment community.

Risk and Control Identification

Lilly would welcome additional guidance and examples regarding the design of an appropriate top-down, risk-based approach to identify key risks for material financial statement misstatements. In particular, we believe additional interpretive Commission guidance for management with concurrent changes to AS2 as summarized below would be most helpful:

- *Reliance on Entity-Level Controls* - We believe greater reliance on entity level and compensating controls and a more practical definition of materiality would help management and auditors consistently identify and assess key risk areas. Although many entity-level controls have been documented and tested, our external auditors are struggling to significantly reduce the transactional testing in any areas. For example, although an account such as Payroll has significant activity flowing through it; it is highly unlikely that Payroll could be materially misstated as it would require significant collusion to be materially misstated. This example could be a perfect area to leverage entity-level controls and potentially eliminate or reduce transactional testing. Therefore, additional guidance on how to leverage effective entity level controls to assist in the reduction of transactional controls testing would be appreciated.
- *Scope of Audit Coverage* - Guidance on risks in determining significant accounts has been limited so far and there are very different interpretations from company to company.

Lilly would like to see additional guidance for scoping coverage related to multiple locations. Assessing the risk for multiple locations is difficult since most of Lilly's international locations individually could not result in a material weakness but in the aggregate could become material. Guidance to balance risk versus sufficient coverage for particular financial statement captions would be helpful. We do not believe there is significant risk in many of our international affiliates individually but must do transactional testing to have sufficient coverage according to our external auditors. For example, a revenue process in the US provides coverage for over 50% of a company's third party sales and an additional eight revenue processes at international affiliates have been documented and tested to achieve the desired 70-80% coverage prescribed. However, each international affiliate would have to misstate their third party sales by over 30% to create a significant deficiency or material weakness for the consolidated financial statements. It is highly unlikely that sales could be materially misstated without identifying the issues through monitoring controls.

- *Reliance on Cumulative Knowledge* – AS2 currently requires each year's audit to "stand on its own" and does not permit the auditor to rely on cumulative knowledge. Most transactional processes do not change from year-to-year. A more efficient top down, risk based approach would be to focus on higher-risk areas and changes in routine processes. A review of process documentation can be utilized each year to determine changes. Processes that have not changed could be eligible for periodic rotational testing. Rotational testing could also be permitted for material, but low risk areas even where changes have occurred assuming appropriate change control

procedures have been followed. We recommend new guidance that allows management and the auditors the flexibility to utilize judgment in determining on an annual basis the appropriate level of testing for lower risk areas. In some areas, this determination may lead to no testing in one year (beyond confirmation of change control procedures).

- *Risk-based Testing of IT Controls* – IT general and automated controls currently require significant repetitive testing and documentation even though experience has shown a failure of a general IT or application control do not directly pose significant financial statement risk. Deficiencies in IT controls, for example, systems access controls, generally are mitigated by other compensating business and/or IT controls. In other words, the failure of one or more key General IT control by themselves rising to the level of materiality to cause a financial misstatement seems more than remote therefore, allowing some degree of flexibility and judgment on IT control scoping seems appropriate. In addition, since COSO does not provide any specific guidance in this area, the degree of needed testing is open to interpretation and additional guidance is needed. Therefore, Lilly would like to see additional guidance on the appropriate application of risk based scoping of IT general and automated application controls. Finally, Lilly would like to see the Commission formally recognize/acknowledge ISACA’s “IT Control Objectives for Sarbanes-Oxley”. This guide is one of the few documents which outline SOx IT compliance. Lilly believes that by having the Commission recognize this guidance, there could be greater alignment and consistency on SOx IT compliance.
- *Fraud Risk Assessment and Controls* - There is limited clear, concise guidance available. Fraud is a very theoretical and subjective area that companies struggled to establish an organized, effective assessment process. To date, there has been inconsistent guidance from the external auditors. Lilly and many companies are still wrestling with basic fraud compliance questions like: How do we draw the line between material and immaterial fraud? How do we separate financial reporting fraud from other fraudulent activities? What is acceptable documentation of fraud risk assessment and controls? Therefore, additional guidance is needed.

Management’s Evaluation

Lilly believes additional interpretive Commission guidance for management with concurrent changes to AS2 related to management’s evaluation could go a long way in creating more effective and efficient approaches. Some of those areas summarized below would be most helpful:

- *Auditor Opinions* - We believe the requirement of two internal control opinions from the external auditors is overly burdensome, redundant and warrants revisiting. Section 404 of the Act requires each registered public accounting firm to “attest to, and report on, the assessment made by management of the issuer”. This has been interpreted during implementation, in conjunction with Section 103 of the Act, to require a standalone auditor opinion on the effectiveness of internal controls. This has clearly added to the cost of compliance, as it requires a level of planning, testing and

documenting by the external auditors that greatly exceeds the level required to evaluate management's assessment.

If an external auditor disagrees with management's assessment, an adverse opinion on management's assessment would be expressed. The scarcity of such adverse opinions in the first two years of SOX 404 compliance indicates that management assessments have been accurate and that a second opinion from the auditor is likely excessive and the incremental cost unjustified. Therefore, we would like additional guidance to allow for more discretionary judgment by the external auditor and management.

- *Point-in-Time Assessment and Roll forward Procedures* – Although the point-in-time assessment was established to allow companies an opportunity to remediate deficiencies identified throughout the year, it has created some unintended consequences of requiring roll forward testing to bring those procedures current as of that point-in-time. Lilly believes more guidance and flexibility should be allowed for lower risk controls which are tested in Q1/Q2. For example, roll forward testing would not be required by the external auditors to complete the internal control assessment as of the end of the year. Instead a written questionnaire or statement confirming no changes have occurred in the processes and controls could be required.

Documentation to Support the Assessment

We agree with the feedback the Commission has received regarding documentation. It was very burdensome in the initial year of compliance, both as a result of too many key controls being identified and auditor requirements, the latter in part driven by their desire for detailed flowcharts and narratives to assist them in conducting required process walkthroughs. Although ongoing maintenance of documentation in year two was somewhat less burdensome than in year one, overall documentation maintenance still remains a significant cost.

Lilly believes the most practical approach to reduce the documentation burden is to move forward with new management guidance and revisions to AS2 that is more risk focused with greater reliance on entity-level and monitoring controls, and revised materiality definitions allowing for higher thresholds. This should significantly reduce the numbers of key processes and controls requiring documentation.

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

Sincerely,

/S/ Arnold C. Hanish
Executive Director, Finance, and
Chief Accounting Officer