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Dear Ms. Morris:

We thank the Commission for the request for feedback and the given chance to raise our voices and express our proposals for potential efficiency increases concerning the implementation of the Sarbanes-Oxley Act of 2002, Section 404.

As we, the Schering AG, were the first German filer and initially filed compliance with Section 404 as of December 31st, 2004, please let us note that we basically share the same level of experience with the implementation of this section and its transition into a regular business activity as the domestic companies.

We hope that our comments and proposals are useful to reduce the burdens of the implementation of Section 404 of the Act, while at the same time not leading to a dilution of the vision and goals that Senate and Congress had in mind while passing it.

We would like to provide the following feedback to the questions raised by the Commission in its recent Concept Release – we have expressed our feedback using the numbers of the questions in the aforementioned Concept Release:

1. In absence of any management guidance or existing court judgements, any even likely applicable literature serves as a basis for developing reasonable own procedures.

   The same holds true for PCAOB's Auditing Standard 2, which serves as a well-thought starting guidance for management to develop their test procedures. However the SEC and the PCAOB already acknowledged that management may use totally different means of evaluating controls and documenting their evaluation than an external independent auditor can use.
   Management can e.g. heavily rely on having the right people in the right place and use personnel evaluation, top-down and bottom-up feedbacks, key performance indicators and training as test documentation.

   An independent auditor cannot apply this grade of reliability to personnel. They will have to review certain specific documentation, re-calculate specific figures, and document all this in working papers consisting of auditor's commented copies of issuer's documentation.

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However, as the aforementioned “acknowledgement” is a recommendation and the PCAOB Auditing Standard 2 language is different, the auditor will not accept such a management testing and in contrary urges management to also review specific documentation, re-calculate specific figures and document all this in working papers consisting of management’s copies of issuer’s documentation. In order to explicitly clarify that management may test controls in a different way than auditors, we propose that an explicit management guidance should incorporate a language that everything described in auditing standard shall be used by auditors, but must not be used by issuers.

We believe that a suitable framework to evaluate the effectiveness of a company’s internal control over financial reporting would be useful for all reporting companies. The framework should use the risk-based and top-down approach as required by PCAOB Auditing Standard Number 2. The framework needs to be fairly general to be applied by all. The framework should leave room for judgement of due professional care and should give clear advices for companies and auditors to adopt it.

We kindly ask to consider that detailed guidance for filers, including hypothetical examples illustrating alternatives available to management that should differ from those available to auditors, would be extremely useful to management teams in their attempts to formulate sound approaches that comply with the objectives of Section 404.

2. We do not believe it is appropriate to hold foreign private issuers to a different standard than their U.S.-based counterparts; however, an extension of the deadline for submission of their first report on the effectiveness of internal control over financial reporting should provide sufficient time to address the unique challenges faced by foreign private issuers.

   We kindly ask the Commission to consider that our company has, like many other private foreign issuers, certifications (ISO, Good Manufacturing Practice (GMP), FDA approvals and so on) within diverse levels of the organisation. The Commission should consider that the usage of the respective documentation and assessment would reduce the effort for the company and the auditors by relying on the work of others.

   The Commissions should give a clear advice for both the companies and the auditors regarding the appropriateness to use the respective documentation and assessment. The considerations should be applicable for all issuers.

3. Based on the experiences of the previous years, the statements of diverse involved parties, the round table discussions and the interactions with the auditors, we believe that an articulation of broad principles is necessary but can give a wide area for interpretations and ongoing discussions. So we would appreciate a detailed interpretive guidance being added to the articulation of broad principles.

4. The Commission included FCPA and additional COSO requirements in the definition of the scope of management’s assessment; by extending this definition, including safeguarding of assets and fraud controls (not meant is management fraud concerning financial statements which is and should be regulated in the Sarbanes-Oxley Act of 2002, but e.g. unfavourable purchase price agreements), management had to not only document and test significant controls ensuring a reliable financial reporting, but also controls over “prevention or timely detection of unauthorized acquisition, use or disposition of the registrant’s assets”.

   While we totally acknowledge the FCPA and the need for such controls, the question may be raised if SOA404 was intended to be used as a means to extend those requirements, especially in the sense of not only having controls in place but regularly testing them and creating an additional liability for management.

We thus suggest narrowing the definition of the “internal controls over financial reporting” to those controls that really have to be in place and operating in order to ensure a reliable presentation of financial statements and corresponding disclosures.

5. We believe that detailed interpretive guidance is much more preferable to prescriptive guidance or generalized rules.

6. We believe that a top-down risk-based approach with sufficient auditing experience has to be the most effective approach to addressing compliance.
   From our experiences the most effective and efficient approaches in assessing ICOFR are:
   - Risk-based approach based on top-down decomposition
   - Suitable risk assessment to reduce the effort for documentation and assessment,
   - Focus the scope of work on the prevention of potential material weaknesses and
   - Focus on key controls.

   To choose a bottom-up approach is not recommendable.

7. We believe that the Commission should enforce a harmonization between the additional guidance that will be issued upon the current feedback-process and the already existing and adopted standards / best practices.

   We kindly ask the Commission to consider that any difficulties arising from a conflict between the Commission's guidance and the guidance of any other standard setting institution (esp. PCAOB) will be more than offset by the fact that the Commission's expectations will be much more clearly understood by both auditors and filers.

8. Within our company the COSO framework was more applicable than others because the COSO framework has been adopted for corporate risk management purposes. In spite off that we believe that companies would benefit from the development of additional framework. It can influence the general considerations within the used framework and can give “new” insights to reduce the work or additional practical advices.

   We would kindly ask you to recognize that useful interpretive comments on the COSO framework can limit the additional effort of the Commission and the PCAOB.

9. The May 16, 2005 and October 6, 2004 guidance issued by the Staff were very helpful and adopted by us.
   The incorporation of the information contained in this guidance into future interpretive guidance has eliminated the need for us to read through multiple theoretical publications, thus increasing efficiency in our assessment process.

10. We totally understand, and support, the incorporation of Section 404(b) and the additional attestation by auditors. Thus, we do not share the view of Canadian standard setters (CSA notice 52-313 to 52-111 and 52-109) that negate the necessity of an independent auditor’s attestation to internal control over financial reporting.

The exact wording of Section 404(b) is “should attest to, and report on, the assessment made by the management of the issuer”. The wording “assessment made by the management” in this context may be interpreted as either “the result of the management’s assessment”, “the process how management comes to any conclusion” or both.

As stated in Mr. Sarbanes “Report together with additional views” [107-205] and no subsequent amendment or explanation in Mr. Oxleys “Conference Report” [107-610], it seems the intention was that “the company’s auditor must report on and attest to management’s assessment of internal controls”. Further is stated: “The Committee intends that the auditor’s assessment of the issuer’s system of internal controls should be considered to be a core responsibility of the auditor and an integral part of the audit report”.
However, SEC [RIN 3235-AI66 and 3235-AI79] and PCAOB [Auditing Standard 2] describe as rule: “The public accounting firm that is required to attest to, and report on, management's assessment of the effectiveness of the company's internal control over financial reporting also will require that the company develop and maintain such evidential matter to support management's assessment.”
The PCAOB consequently interprets further: “If the auditor concludes that management has not fulfilled the responsibilities enumerated in the preceding paragraph, the auditor should communicate, in writing, to management and the audit committee that the audit of internal control over financial reporting cannot be satisfactorily completed and that he or she is required to disclaim an opinion. Paragraphs 40 through 46 provide information for the auditor about evaluating management's process for assessing internal control over financial reporting.” (Sec. 21 of Auditing Standard 2).

This language in the SEC and PCAOB rulings leads to the following situation: Management has sufficient internal controls in place, financial reporting is materially reliable, the auditors attest unqualified on financial reporting and internal controls. However, some tests of management assessment were not documented, or not based on a – from an auditor’s view – sufficient sample sizes, or – from an auditor’s view – not executed with the correct test methods, so the auditor may raise a qualified opinion or even in worst case disclaim an opinion on internal controls (even if they already audited them positively).

To support this language, PCAOB Board Member Mr. Gillan said in a speech at the SEC Institute in June 2005: “the independent auditor must also now publicly attest to the accuracy of the corporate certification”.

This “additional” attestation (it’s the third independent auditors attestation: (1) financial reporting, (2) internal controls, (3) management’s procedures to evaluate internal controls) seems to represent not only the topic that could be described as the root-cause of implementation problems, but is also irritating:

With this attestation comes no additional liability, as management is already liable for having internal controls and an annual assessment and the auditor additionally attests to internal controls with all material weaknesses – in case of different opinions between management and the auditor even additional weaknesses – presented in the auditor’s report. However, this third attestation causes auditors to permanently tell management what management has to do – else, due to the language in the PCAOB Auditing Standard 2, the auditor may disclaim an opinion on internal control over financial reporting.

Further, shareholders do not receive higher reliability on financial reporting by this third attestation, as they already know about the financial reporting and the internal controls. This third attestation comes at very high cost. Not only that auditors are auditing internal controls, they are also heavily reviewing management’s documentation, sample sizes, documentation of how management draws samples, management testing procedures, every wording in management’s documentation. But this is not the end: After identifying that for any control the test procedures of management (or sample size) may not have been the same as the auditor would have applied, they are forcing the issuer to re-assess and re-document the control. This happens even if auditors know that the control has operated effectively.

The SEC and PCAOB in the May 16, 2005 statements already acknowledged that management may completely use different methods of evaluating internal controls that auditors cannot use. However, the aforementioned language leads to this statement being obsolete as practically there won't be any changes.

We thus propose to interpret Section 404(b) in a way that the auditor has to attest to, and report on, the effectiveness of internal controls over financial reporting and not the process, how management comes to any conclusion.

An other aspect to consider are the compliance costs for us as foreign accelerated filers. We believe the compliance costs were significantly impacted by inefficiencies that resulted from a lack of interpretive guidance for filers and efforts were impacted by the scope and diversity of our operations and the resulting complexity of our financial reporting.

11. We believe that the general guidance to implement the "top-down" and "risk-based approach" to identify risks of reliable financial reporting, fraud issues and safeguarding of assets is suitable. An additional industry-specific guidance with detailed examples containing all relevant risk areas including considerations of high, middle and low risk areas would be helpful.

12. We believe an additional guidance on identifying key controls that address the Financial Statements risk would be useful in a way, that a business transaction / (sub-) process oriented subset of key controls enables the filers to gather the compliance within the Section 404 in an efficient manner.

    We would kindly ask the Commission to consider that the subset should define risks and respective key controls. Alternatively the Commission should provide references within sufficient public sources. However, due professional care and professional judgment will always be required and even in light of additional guidance, registrants and auditors might come to different conclusions.

13. Due to the fact that we have no sufficient experiences with the "needs" of smaller public companies we will pass this point.

14. Due to the fact that we have no sufficient experiences with the "needs" of smaller public companies we will pass this point.

15. We believe that the Commission should increase the considerations of entity-level controls. Guidance issued by the PCAOB subsequent to Audit Standard 2 has addressed the importance of entity-level controls in combination with the risk-based approach. This supplemental guidance is on a very high-conceptual level. Indeed the guidance of Audit Standard 2 provides numerous detailed examples of designing audit testing without references to entity-level controls but an appropriate guidance regarding a suitable combination of entity-level and transaction-level controls is missing.

    From our point of view such a guidance, applicable for both, companies and auditors, should be the chance to reduce the additional burdens of the Section 404 without reducing the investor reliance in the effectiveness of internal control over financial reporting.

16. We strongly recommend that the Commission should give binding guidance/rules for quantitative and qualitative factors:
    - Likelihood of an error,
    - Magnitude of an error etc.

    The binding guidance/rules should be given for assessing risks / identifying controls on one hand and on the other hand to evaluate the risk mitigating controls.
    The Commission should address similar factors as given in the diverse standards of rule setting organization (AICPA, IIA etc.)
    Additionally we believe that interpretive guidance which includes examples of circumstances when an account balance might not be considered significant, despite the fact that the balance exceeds some specific quantitative measure, would be useful.

    Due to the fact that we have no sufficient experiences with the “needs” of smaller public companies we will pass this point.

17. As discussed in the answer of question number four, we thus suggest narrowing the definition of the “internal controls over financial reporting” to those controls that really have to be in place and operating in order to ensure a reliable presentation of financial statements and corresponding disclosures.

    The Commission has, in the definition of the scope of management’s assessment, extended this definition by including fraud controls (not meant is management fraud concerning financial statements which is and should be regulated in the Sarbanes-Oxley Act of 2002, but e.g. unfavourable purchase price agreements).

    Management had to not only document and test significant controls ensuring a reliable financial reporting, but also controls over “prevention or timely detection of unauthorized acquisition”.

    We totally acknowledge the need for such controls. The question may be raised if SOA404 was intended to be used as a means to extend those requirements, especially in the sense of not only having controls in place but regularly testing them and creating an additional liability for management.
    We kindly ask you to give clear advice what kind of fraud preventive and detective controls should be in place or give a binding reference as mentioned above (guidance issued by the AICPA Fraud Task Force entitled “Management Antifraud Programs and Controls”).
    Please consider that this guidance should be efficient, easy to use and limit the additional efforts for the filers.

18. The guidance within Auditing Standard 2 “Tests to be Performed When a Company Has Multiple Locations or Business Units” is written in a general manner. Based on the information of the Appendix B the auditors should for example consider:
    - Location or business unit has a relative financial significance,
    - Specific significant risks,
    - Risk of material misstatement,
    - Determine the other locations or business units that, when aggregated, represent a group with a level of financial significance that could create a material misstatement in the financial statements.

    To deal with the issues above in a suitable manner we believe it’s indispensable that the Commission should give clear guidance on:
    - Thresholds to identify locations or business units with a relative financial significance,
    - Detailed industry-specific subsets of specific significant risks (in form of a checklist) including guidance for the implementation
    - Detailed subset of risks of material statements including guidance for the implementation.

- Threshold to determine the other locations or business units that, when aggregated, represent a group with a level of financial significance that could create a material misstatement in the financial statements.

In this context we recommend the Commission that the auditors and the filers need a specific guideline for measuring the terms “material”, “reasonable”, “significant” and “sufficient” in the context of internal control over financial reporting for issuers, including, but not limited to
- reference to specific examples of the appropriate application of those terms;
- establishment of a means for a timely response by the Commission or Board, as applicable, to requests by issuers and registered public accounting firms for guidance as to the appropriate application of those terms;

Our company has a large number of individually insignificant locations. In this circumstance there was a significant amount of healthy debate regarding the number of locations to be tested as well as both individual and aggregated sample sizes for specific controls, that operated at all of the individually significant locations. Interpretive guidance that addresses this topic might be useful for registrants with similar business structures.

19. We agree with the tendency of the opinion from the PCAOB regarding company-level-controls / entity-level-controls (Auditing Standard 2 paragraph 52-54).

    Additionally we would kindly ask you to provide a detailed guidance for entity-level controls to reduce the transaction-level controls in a way that the filers can focus on entity-level controls. From our point of view a comprehensive set of entity-level controls with sufficient implementation instructions would reduce the uncertainty of the filer regarding an appropriate mixture of entity-level controls and transaction-level (“key”) controls.

    We believe that in addition this kind of guidance would provide the auditors with a sufficient guideline to evaluate the management assessment and can focus and reduce the auditors work.

    For example a strong budgeting process with bottom-up planning and top-down evaluation / verification and budget monitoring containing a suitable documented and assessed control structure can reduce transaction-level controls in:
    - the procurement process (vendor selection, purchase requisition),
    - the tangible asset management (capital expenditure additions)
    - the sales / revenue recognition process and so on.

    We kindly ask the Commission to consider that the external auditors may completely use different policies and procedures for their audit than management and also may apply different documentation policies; a 1:1 application of standards for management and auditors on the other hand raises difficulties in implementation.

20. We believe that the majority of daily interactions are transaction-level controls. If the Commission agrees with our point of view regarding the usage of entity-level controls (as mentioned in comment to question number 19), the issuer can reduce the assessment of transaction-level controls and can focus on suitable entity-level controls such as assignment of authority and responsibility, consistent policies and procedures, code of ethics and business conduct and fraud prevention, activities of the internal audit function, the audit committee and self-assessment programs.

    We believe that most useful in ongoing monitoring of control effectiveness are e.g. the activities of:
    - the Audit Committee,
    - the Internal Audit Functions,

- the Risk Management Functions,
- the Controlling Functions with diverse management levels,
- the Compliance Monitoring Functions (e.g. Compliance Officers) and so on.

We kindly ask the Commission to consider that based on our experiences the majority of the companies are using the self assessment approach. Therefore the level of confidence for an evaluation of ICOFR-purposes should be higher in cases management uses ongoing monitoring of controls effectiveness.

21. Due to the fact that we have no sufficient experiences with the “needs” of smaller public companies we will pass this point.

22. We believe that a suitable evaluation framework is required to give a clear guidance for the filers and the auditors. Integral parts of the evaluation framework should be:
- thresholds regarding the materiality,
- guidance regarding the likelihood and magnitude of risks impacted by control gaps and
- guidance regarding the exceptions found in testing.

23. We kindly ask the Commission to provide guidance on the timing of entity level and process level testing and application of the “as of approach” to assessment. The “as of approach” is strictly applied to process level testing and has a significant impact if changes are planned or executed around the 31 December period. The “as of” requirement has a significant impact on the plans for implementing new systems or controls in the second half of the accounting period too.

Guidance should be useful to clarify what kind of retesting is required. In addition, guidance indicating that management may rely on entity level controls over change management procedures rather then re-perform testing in the current year if the controls were tested in the prior year would be beneficial.
The given guidance by the Commission and the PCAOB implies that key controls have been tested at least once in the fourth quarter.

Based on our experiences of the last two years we believe the risk of finding a material weakness or significant deficiency is significant lower when these key controls are tested during the year without findings and exceptions.
Therefore we kindly ask the Commission to provide guidance that enforces testing of internal controls throughout the year, based upon assessed risk considering significant changes during the fourth quarter.

We especially want to stress the importance of such guidance for foreign-private issuers as the form 20-F is – in contrary to the domestic filer forms – only issued once a year.

24. We kindly ask the Commission to provide a framework for the evaluation of control exceptions and deficiencies. The framework should give guidance in a clear and sound manner so that it is usable without need for interpretations at all levels of management. Additionally the framework should give guidance for implementation and a suitable set of best practice examples.

Due to the missing practice-based guidance the evaluation of identified internal control deficiencies and the qualification as a deficiency, a significant deficiency and a material weakness is focused on the auditors opinion.

25. Based on our experiences the issuer is unable to use the guidance of Auditing Standard 2 to evaluate the identified deficiencies as required within the standard without specific auditing experiences.

    The companies have no benchmarks for distinguishing material weaknesses or significant deficiencies. Therefore we kindly ask the Commission to provide a specific guidance by considering the following points:
    - Thresholds for qualifying a deficiency as a material weakness e.g. based on percentage of consolidated revenue and/or profit before taxes
    - Thresholds for qualifying a deficiency as a significant deficiency in the same manner as outlined above
    - Thresholds for qualifying a combination of significant deficiencies as a material weakness.

26. From our point of view the financial statements closing process is one of the most critical and significant processes within our company. Usually this process contains strong oversight and analytical controls within the top management to ensure reliable financial statements and corresponding disclosures.

    Therefore an additional guidance on factors that management should consider when determining whether they could conclude that no material weakness exists despite the discovery of a need to correct a financial statements error as part of the financial statements closing process would be necessary.

27. We would appreciate that the Commission gives a specific guidance addressing the circumstances under which a restatement of previously reported financial information would not lead to the conclusion that a material weakness exists in the company's internal control over financial reporting.
    We kindly ask the Commission to consider this item in conjunction with our comments on the item 25.

28. We believe that companies are able o use technology to gain efficiency in evaluating the effectiveness of internal controls through industry-specific benchmarking e.g. key performance indicators and Financial Statement analysis on one hand but on the other hand by using software solutions to aggregate the evaluation results over the company structure.

29. We have decided to use the COBIT provided by ISACA. From our point of view the recommendations within COBIT are oversized for SOA 404 purposes. There is a tendency concerning IT general controls, due to the undifferentiated and over-usage of the term "pervasive", to ascribe too much significance to IT general control risks in comparison to financial statement risks. By their nature, IT general controls are somewhat removed from direct linkage to financial statement assertions.

    It' s common sense that IT general controls are critical to support computerized applications that are generally an integral part of a company's system of ICOFR.

    In absence of a detailed guidance we have made the experiences that this non-existent linkage creates difficulties for the company and the external auditors in trying to define the scope for IT general controls.

    Those IT general controls should focus on risks that are at least reasonably likely to be the root cause of an undetected material error in the financial statements.

30. Our company has utilized the COBIT framework in the course of our evaluation of IT general controls. While many elements of the framework constitute "best practices" as opposed to minimum required

controls, we have generally reached consensus with our auditors regarding the elements of the COBIT framework that are relevant to our compliance efforts.

31. The Commission should consider that management would benefit from guidance on the appropriate and required levels of documentation to support their assertion on the effectiveness of internal control over financial reporting.

    The Commission should clarify the overall objectives of the documentation, including factors that might influence documentation requirements and other common documentation concerns.

    We have prepared narratives or flowcharts as well as objective-risk-control matrices. While the narratives might not have been necessary to identify controls for testing, they were generally prepared because no other documentation existed describing the activities. From our point of view these narratives served as a basis for the efficient preparation und understanding of objective-risk-control matrices (which were used to identify controls for testing) as well as the purpose of providing our personnel with an understanding of specific responsibilities, thus contributing to the overall strength of the system of internal controls.

    The Commission should give a clear advice to ensure that the whole documentation has to enable a reasonably knowledgeable individual to understand the business processes, the risk and control structure.

    We believe that the implementation of the „key control concept“ would reduce the costs of SOA Section 404 implementation significantly and give a deeper understanding / acceptance of a risk-based ICOFR. The identification of key controls is important to an efficient and effective Section 404 compliance. An overly conservative approach, where too many controls are defined as “key,” will result in excessive time and resources testing controls that are not critical to the assessment.

    On the other hand, if too few controls are identified, this may result in an additional effort when the external auditor identifies, and management then agrees with, the need for additional key controls. Therefore a major topic for the whole exercise is a suitable understanding of the key control concept, of the business case and the corresponding financial statements risks. A detailed risk analysis enables the company to detect the financial statements risks and helps to identify key controls.

    An industry specific guidance with a suitable subset of key controls including a detailed explanation should be considered.

32. We believe that a „rough cut“ documentation guidance should be developed that management must maintain as evidence for its assessment of risks to financial reporting and control identification. A major underlying assumption should be that the auditor has a suitable understanding of the client’s business processes so that the documentation of the control documentation and control assessment can focus on the substantial parts.

    In absence of a clear written guidance for us, auditors interpret the regulations of the Commission and the PCAOB for Section 404 as “all you can provide approach”. This approach results in an overburdened documentation exercise with significant investments in archiving structures enforced by missing guidance for the record retention period.

33. We believe that the guidance is needed on the extent of documentation that management must maintain for its evaluation procedures that support the annual assessment of internal control over financial reporting. The guidance should give clear advice on the documentation requirements for the following topics, but not limited to:

- the evaluation of the design of each of the five COSO components of the company's internal control over financial reporting;
- the process used to determine significant accounts and disclosures and major classes of transactions, including the determination of the locations or business units at which to perform testing;
- the identification of the points at which misstatements related to relevant financial statements assertions could occur within significant accounts and disclosures and major classes of transactions;
- the evaluation of entity-level controls;
- the evaluation of transaction-related controls;
- the work performed by others and
- the evaluation of any identified deficiencies.

34. We kindly ask the Commission to provide detailed guidance for both the documentation and the assessment of information technology controls.
    The Commission should consider whether it’s sufficient to make references to existing documentation (not developed for SOA Section 404 purposes) for information technology controls (e.g.: IT development & maintenance regulations, IT operation handbook etc.) on one hand and on the other hand to assessments made by trusted third parties (e.g. ISO, FDA etc.) to be in compliance with Act.

35. Due to the fact that we have no sufficient experiences with the “needs” of smaller public companies we will pass this point.

Based on our experiences it would be sufficient to assess all transaction-level controls not for every accounting period. A rotation of the assessment for the transaction-level controls in the different business sub-processes / business sub-cycles could reduce the work of management and auditors in a significant manner. We would stress that for such business sub-processes / business sub-cycle where the assessment of transaction-level will pass, a suitable assessment of entity-level controls should be in place.

This testing approach is comparable with the process/risk-oriented audit approach by the big 4 audit companies to gather sufficient audit evidence for the Financial Statements Audit.

If you have any questions regarding the information contained in this letter, please feel free to contact Michael Syska at +49 30 468 16155 or Michael Schwartz +49 30 468 16153.

Kind regards,

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