Life Sciences
Accounting and Financial Reporting Update — Interpretive Guidance on PCAOB Changes to the Auditor’s Report
March 2018
PCAOB Changes to the Auditor’s Report

In June 2017, the PCAOB adopted a new auditing standard on the auditor’s report (the “standard” or “release”). While retaining the current “pass/fail” opinion of the existing auditor’s report, the standard includes several significant modifications, which are intended to increase the informational value, usefulness, and relevance of the auditor’s report. The key changes to the auditor’s report under the standard are:

- Standardized ordering and inclusion of section headers, with the opinion section appearing first.
- Enhanced descriptions of the auditor’s role and responsibilities, including a statement regarding independence requirements.
- Communication of critical audit matters (CAMs).
- Disclosure of auditor tenure (the year in which the auditor began serving consecutively as the company’s auditor).

**Critical Audit Matters**

A CAM is defined in the standard as “any matter arising from the audit of the financial statements that was communicated or required to be communicated to the audit committee and that relates to accounts or disclosures that are material to the financial statements and involved especially challenging, subjective, or complex auditor judgment.”

The release also states that CAMs could include matters that were (1) required to be communicated to the audit committee and (2) actually communicated, even if not required. Further, the standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

CAMs will be identified and described in a separate section in the auditor’s report titled “Critical Audit Matters.” Specific language will precede the description of the CAMs, stating that (1) CAMs do not alter the opinion on the financial statements and (2) the auditor is not providing a separate opinion on the CAMs or the accounts or disclosures to which they relate. The release states that for each CAM communicated in the auditor’s report, the auditor will be required to:

- “Identify the [CAM].”
- “Describe the principal considerations that led the auditor to determine that the matter is a [CAM].”
- “Describe how the [CAM] was addressed in the audit.”
- “Refer to the relevant financial statement accounts or disclosures that relate to the [CAM].”

The release also states that the determination of a CAM “should be made in the context of [a] particular audit, with the aim of providing audit-specific information rather than a discussion of generic risks.” It is expected that in most audits to which the CAM requirements apply (see applicability information below), the auditor would identify at least one CAM. If no CAMs are identified, the auditor would be required to make a statement to that effect in the auditor’s report.
**Auditor Tenure**

The standard requires the auditor to include a statement in the auditor's report containing the year the auditor began serving consecutively as the company's auditor. However, the location for this statement in the auditor's report is not prescribed.

**Effective Date**

The effective date is being phased in as follows:

- All changes except for communication of CAMs: audits of fiscal years ending on or after December 15, 2017.

- Communication of CAMs:
  - Audits of large accelerated filers (as defined by the SEC): fiscal years ending on or after June 30, 2019.
  - Audits of all other companies: fiscal years ending on or after December 15, 2020.

However, the release states that auditors may elect to comply with the standard before its effective date at any point after SEC approval.

Communication of CAMs is not required for audits of emerging growth companies as defined in Section 3(a)(60) of the Securities Exchange Act of 1934. However, the standard permits voluntary inclusion of CAMs in the auditor's report for such entities. All other provisions of the standard apply to audits of these entities.

**Considerations for Management and Audit Committees**

Although the standard will be implemented in accordance with phased-in effective dates, management and audit committees will most likely want to start to consider the implications of the new requirements and discuss them with their auditors. Potential questions regarding CAMs may include the following:

- What matters could be CAMs?
- How will management and audit committees engage with the auditor as CAMs are identified and the auditor’s descriptions of the CAMs are developed and finalized?
- How will the timing of auditor communications with management and the audit committee accommodate the discussion of CAMs?
- How do the auditor’s statements regarding CAMs compare with management’s disclosures regarding the same matters?

For more information about the PCAOB changes to the auditor's report, see Deloitte's June 20, 2017, *Heads Up*. 
Appendix A — Glossary of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

**AICPA Literature**

Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities*

AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*

*AICPA Technical Questions and Answers*, Q&A paragraph 2260.03, “Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit”

**FASB Accounting Standards Updates (ASUs)**


**ASU 2018-01**, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*

**ASU 2017-12**, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

**ASU 2017-11**, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

**ASU 2017-09**, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*

**ASU 2017-07**, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

**ASU 2017-05**, *Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets*

**ASU 2017-04**, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

**ASU 2017-01**, *Business Combinations (Topic 805): Clarifying the Definition of a Business*
ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*


ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*


ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Recession of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*

ASU 2016-08, *Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*

ASU 2016-02, *Leases (Topic 842)*


ASU 2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*


ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity — a consensus of the FASB Emerging Issues Task Force*

ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation

ASU 2014-09, Revenue From Contracts With Customers (Topic 606)

ASU 2014-02, Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council

ASU 2011-06, Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers — a consensus of the FASB Emerging Issues Task Force

ASU 2010-27, Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers — a consensus of the FASB Emerging Issues Task Force

ASU 2010-20, Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses

ASU 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force

**FASB Accounting Standards Codification (ASC) Topics**

ASC 205, Presentation of Financial Statements

ASC 210, Balance Sheet

ASC 220, Income Statement — Reporting Comprehensive Income

ASC 230, Statement of Cash Flows

ASC 235, Notes to Financial Statements

ASC 250, Accounting Changes and Error Corrections

ASC 260, Earnings per Share

ASC 280, Segment Reporting

ASC 320, Investments — Debt and Equity Securities

ASC 321, Investments — Equity Securities

ASC 323, Investments — Equity Method and Joint Ventures

ASC 325, Investments — Other

ASC 326, Financial Instruments — Credit Losses

ASC 330, Inventory

ASC 350, Intangibles — Goodwill and Other

ASC 360, Property, Plant, and Equipment

ASC 410, Asset Retirement and Environmental Obligations
Appendix A — Glossary of Standards and Other Literature

ASC 420, Exit or Disposal Cost Obligations
ASC 450, Contingencies
ASC 470, Debt
ASC 480, Distinguishing Liabilities From Equity
ASC 505, Equity
ASC 605, Revenue Recognition
ASC 606, Revenue From Contracts With Customers
ASC 610, Other Income
ASC 715, Compensation — Retirement Benefits
ASC 718, Compensation — Stock Compensation
ASC 720, Other Expenses
ASC 730, Research and Development
ASC 740, Income Taxes
ASC 805, Business Combinations
ASC 808, Collaborative Arrangements
ASC 810, Consolidation
ASC 815, Derivatives and Hedging
ASC 820, Fair Value Measurement
ASC 825, Financial Instruments
ASC 830, Foreign Currency Matters
ASC 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 915, Development Stage Entities
ASC 958, Not-for-Profit Entities
ASC 985, Software
**Proposed FASB Accounting Standards Updates (Proposed ASUs)**

Proposed ASU 2018-200, Leases (Topic 842): Targeted Improvements


FASB Proposed Accounting Standards Update 2017-280, Consolidation (Topic 812): Reorganization


Proposed ASU 2017-220, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

Proposed ASU 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory

Proposed ASU 2017-200, Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)


Proposed ASU 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance

Proposed ASU 2015-310, Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material

**Other FASB Proposal**


**FASB Statements (Pre-Codification Literature)**

Statement No. 167, Amendments to FASB Interpretation No. 46(R)

Statement No. 160, Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51

Statement No. 141(R), Business Combinations

**FASB Interpretations (Pre-Codification Literature)**

FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109

FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities
**FASB Concepts Statements**
No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 6, *Elements of Financial Statements*

**EITF Issues (Pre-Codification Literature)**
Issue 09-4, “Seller Accounting for Contingent Consideration”

Issue 08-1, “Revenue Arrangements With Multiple Deliverables”

Issue 04-5, “Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights”

Issue 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”

Issue 01-8, “Determining Whether an Arrangement Contains a Lease”

Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

**PCAOB Auditing Standard**

**SEC C&DI Topic**
Non-GAAP Financial Measures

**SEC Interpretive Release**
33-10403, *Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*

**SEC Regulation G**
“Conditions for Use of Non-GAAP Financial Measures”

**SEC Regulation S-K**
Item 10(e), “General; Use of Non-GAAP Financial Measures in Commission Filings”

Item 103, “Business; Legal Proceedings.”

**SEC Regulation S-X**
Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired”

Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired”
Rule 4-08(g), “General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

Rule 4-08(h), “General Notes to Financial Statements; Income Tax Expense”

**SEC Staff Accounting Bulletins (SABs)**

SAB Topic 1.1.M, “Financial Statements; Materiality”

SAB Topic 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

SAB Topic 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”

SAB Topic 13, “Revenue Recognition”

SAB Topic 13.A.4, “Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price”

SAB Topic 13.B, “Revenue Recognition; Disclosures”

SAB 116, “Staff Accounting Bulletin No. 116”

SAB 118, codified as SEC Staff Accounting Bulletin Topic 5.EE, “Miscellaneous Accounting; Income Tax Accounting Implications of the Tax Cuts and Jobs Act”

**Internal Revenue Code (IRC)**

IRC Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”

IRC Section 163(j), “Interest; Limitation on Business Interest”

IRC Section 199, “Income Attributable to Domestic Production Activities”

IRC Section 383, “Special Limitations on Certain Excess Credits, Etc.”

IRC Section 787, “Termination of Private Foundation Status”

IRC Section 965, “Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation”

IRC Section 4191, “Medical Devices”

**International Standards**

IFRS 16, *Leases*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*
## Appendix B — Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AFS</td>
<td>available for sale</td>
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<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
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<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
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<tr>
<td>AOCI</td>
<td>accumulated other comprehensive income</td>
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<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
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<td>APIC</td>
<td>additional paid-in capital</td>
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<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
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<td>ASU</td>
<td>FASB Accounting Standards Update</td>
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<td>BCF</td>
<td>beneficial conversion feature</td>
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<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
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<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
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<td>BPD</td>
<td>branded prescription drug</td>
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<td>BOLI</td>
<td>bank-owned life insurance</td>
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<td>CAM</td>
<td>critical audit matter</td>
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<td>C&amp;DI</td>
<td>SEC Compliance and Disclosure Interpretation</td>
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<td>CECL</td>
<td>current expected credit loss</td>
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<td>CFC</td>
<td>controlled foreign corporation</td>
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<td>CODEM</td>
<td>chief operating decision maker</td>
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<td>COLI</td>
<td>corporate-owned life insurance</td>
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<td>CRO</td>
<td>contract research organization</td>
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<td>CTA</td>
<td>cumulative translation adjustment</td>
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<td>DCPs</td>
<td>disclosure controls and procedures</td>
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<td>DTA</td>
<td>deferred tax asset</td>
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<tr>
<td>DTL</td>
<td>deferred tax liability</td>
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<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
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<tr>
<td>EITF</td>
<td>FASB Emerging Issues Task Force</td>
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<tr>
<td>E&amp;P</td>
<td>earnings and profits</td>
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<td>EPS</td>
<td>earnings per share</td>
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<td>EU</td>
<td>European Union</td>
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<td>FAQ</td>
<td>frequently asked question</td>
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<td>FASB</td>
<td>Financial Accounting Standards Board</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FDII</td>
<td>foreign derived intangible income</td>
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<tr>
<td>FIFO</td>
<td>first in, first out</td>
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<td>FIN</td>
<td>FASB Interpretation Number (superseded)</td>
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<td>FOB</td>
<td>free on board</td>
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<td>GAAP</td>
<td>generally accepted accounting principles</td>
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<td>GILTI</td>
<td>global intangible low-taxed income</td>
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<td>GPO</td>
<td>group purchasing organization</td>
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<td>IAS</td>
<td>International Accounting Standard</td>
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<td>IASB</td>
<td>International Accounting Standards Board</td>
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<td>IFRS</td>
<td>International Financial Reporting Standard</td>
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<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
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<td>IP</td>
<td>intellectual property</td>
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<tr>
<td>IPO</td>
<td>initial public offering</td>
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<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
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<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
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<td>IRS</td>
<td>Internal Revenue Service</td>
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<tr>
<td>IT</td>
<td>information technology</td>
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<tr>
<td>LIFO</td>
<td>last in, first out</td>
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<tr>
<td>LLC</td>
<td>limited liability company</td>
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### Abbreviation Description

<table>
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<tbody>
<tr>
<td>LP</td>
<td>limited partnership</td>
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<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
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<tr>
<td>MD&amp;A</td>
<td>Management’s Discussion and Analysis</td>
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<td>MDET</td>
<td>medical device excise tax</td>
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<td>MSL</td>
<td>medical science liaison</td>
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<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
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<tr>
<td>NOL</td>
<td>net operating loss</td>
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<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<tr>
<td>PBE</td>
<td>public business entity</td>
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<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
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<tr>
<td>PCC</td>
<td>Private Company Council</td>
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<tr>
<td>PCD asset</td>
<td>purchased financial asset with credit deterioration</td>
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<td>PRV</td>
<td>priority review voucher</td>
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<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PTRS</td>
<td>probability of technical and regulatory success</td>
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<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
</tr>
<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
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<tr>
<td>ROU</td>
<td>right-of-use</td>
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<tr>
<td>SAB</td>
<td>SEC Staff Accounting Bulletin</td>
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<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<td>SFC</td>
<td>specified foreign corporation</td>
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<tr>
<td>SIFMA</td>
<td>Securities Industry and Financial Markets Association</td>
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<tr>
<td>T.D.</td>
<td>Treasury Decision</td>
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<td>TRG</td>
<td>transition resource group</td>
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<td>UTB</td>
<td>unrecognized tax benefit</td>
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<td>VIE</td>
<td>variable interest entity</td>
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<td>WAC</td>
<td>wholesaler acquisition cost</td>
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