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Life Sciences Industry Accounting Guide

Leases

March 2025

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Preface

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the life sciences industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2025 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting and rulemaking developments (through March 7, 2025), and key differences between U.S. GAAP and IFRS® Accounting Standards. Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2024 edition are summarized in Appendix D.

We hope the Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

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Chapter 10 — Leases

10.1 Overview

10.1.1 Background

In February 2016, a month after the IASB issued IFRS 16 on accounting for leases, the FASB issued its own final standard on accounting for leases (the "leasing standard" or the "standard") as ASU 2016-02 (codified as ASC 842). The primary objective of the standard was to address the off-balance-sheet financing concerns related to lessees' operating leases. Accordingly, except for those leases that qualify for the short-term lease exemption under ASC 842 (i.e., certain leases with a lease term of 12 months or less), the standard's lessee model requires lessees to adopt a right-of-use (ROU) asset approach that brings substantially all leases onto the balance sheet. Under this approach, a lessee records an ROU asset representing its right to use the underlying asset during the lease term and a corresponding lease liability in a manner similar to the current approach for capital leases.

The FASB also addressed questions such as:

- Whether an arrangement is a service or a lease.
- What amounts should be initially recorded on the lessee's balance sheet for the arrangement.
- How to reflect the effects of leases in the statement of comprehensive income.
- How to apply the resulting accounting in a cost-effective manner.

Further, the leasing standard aligns certain underlying principles of the lessor model with those in ASC 606, the FASB's revenue recognition standard, including those related to the evaluation of how collectibility should be considered and the determination of when profit should be recognized.

10.1.2 Scope

The scope of ASC 842 encompasses leases, including subleases, of all PP&E. It does not include leases of or for the following:

- Intangible assets.
- Exploration for or use of minerals, oil, natural gas, and similar nonregenerative resources.
- Biological assets.
- Inventory.
- Assets under construction.

10.1.3 Definition of a Lease

The leasing standard states that a contract is, or contains, a lease if the contract gives a customer "the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration." Control is considered to exist if the customer has both of the following:

- "The right to obtain substantially all of the economic benefits from use of [an] identified asset."
- "The right to direct the use of the identified asset."

An entity is required at inception to identify whether a contract is, or contains, a lease. The entity will reassess whether the contract is, or contains, a lease only in the event of a modification to the terms and conditions of the contract.

The table below summarizes key concepts related to the definition of a lease.

Concept	Requirement	Observation
Use of an identified asset	An asset is typically considered to be an identified asset if it is explicitly specified in a contract or implicitly specified at the time the asset is made available for use by the customer. However, if the supplier has substantive rights to substitute the asset throughout the period of use **and** would benefit economically from substituting that asset, the asset is not considered "identified," and there is no lease for accounting purposes (see below).	An entity does not need to be able to identify the particular asset (e.g., by serial number) but must instead determine whether an identified asset is needed to fulfill the contract. Distinguishing between a lease and a capacity contract requires significant judgment. The standard clarifies that a capacity portion of an asset is an identified asset if it is physically distinct (e.g., a specific floor of a building). On the other hand, a capacity portion of a larger asset that is not physically distinct (e.g., a percentage of a pipeline) is not an identified asset unless that portion represents substantially all of the asset's capacity.
Substantive substitution rights	A supplier's right to substitute an asset is substantive only if both of the following conditions exist: • The supplier has the practical ability to substitute alternative assets throughout the period of use. • The supplier would benefit economically from the exercise of its right to substitute the asset.	The FASB established this requirement because it reasoned that if a supplier has a substantive right to substitute the asset throughout the period of use, the supplier — not the customer — controls the use of the asset. It is often difficult for a customer to determine whether a supplier's substitution right is substantive. A customer should presume that a substitution right is not substantive if it is impractical to prove otherwise.

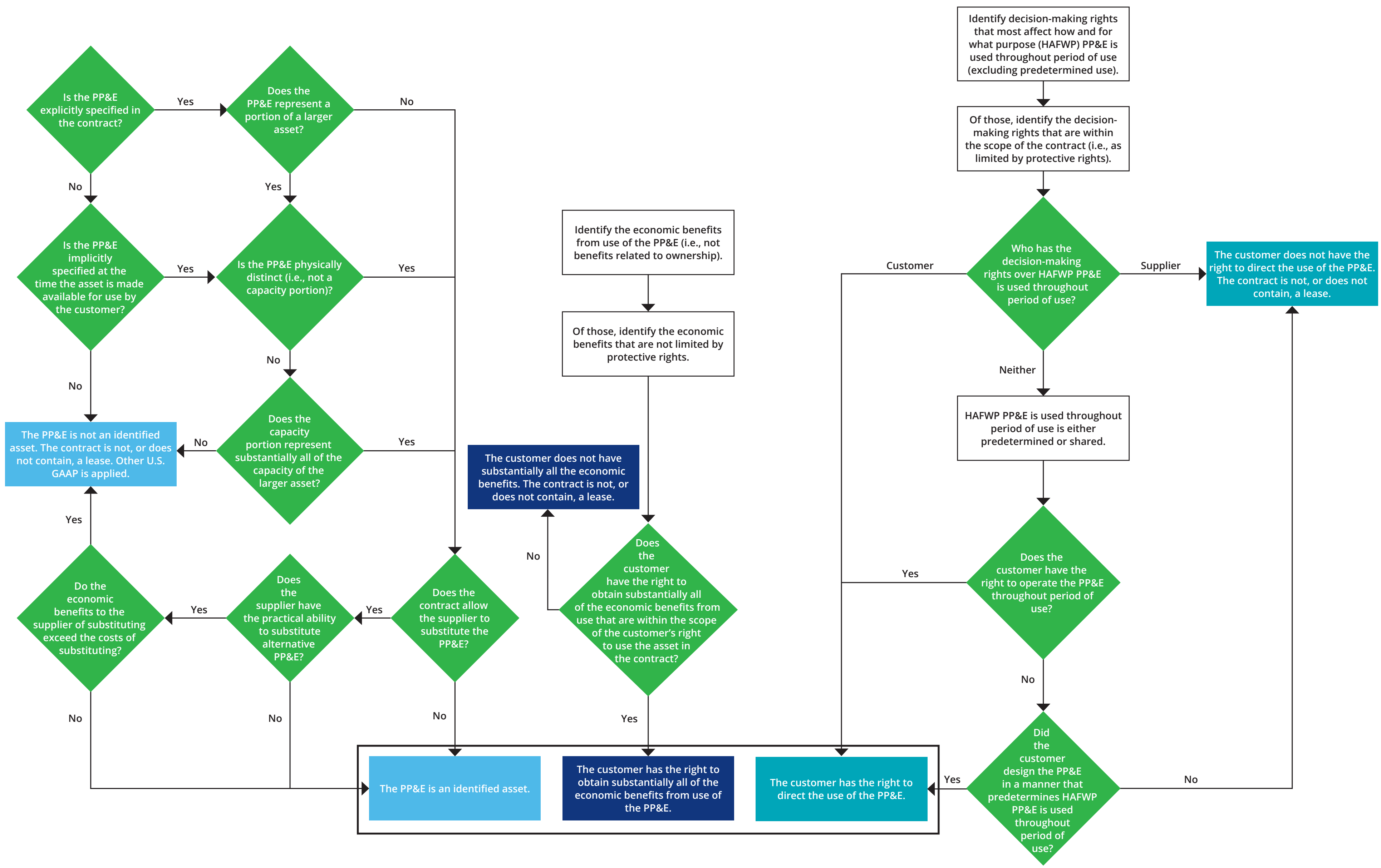
(Table continued)

Concept	Requirement	Observation
Right to obtain economic benefits from use of the identified asset	To control the use of an identified asset, a customer must have the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use. The term “substantially all” is generally 90 percent of the economic benefits of the asset.	The economic benefits from use of an asset include the primary output and by-products of the asset as well as other economic benefits from using the asset that could be realized from a commercial transaction with a third party.
Right to direct the use of the identified asset	A customer has the right to direct the use of an identified asset throughout the period of use if either of the following conditions exists: • The customer has the right to direct “how and for what purpose” the asset is used throughout the period of use. • The relevant decisions about how and for what purpose the asset is used are predetermined and (1) the customer has the right to operate (or direct others to operate) the asset throughout the period of use and the supplier does not have the right to change the operating instructions or (2) the customer designed the asset in a way that predetermines how and for what purpose the asset will be used.	The relevant rights to be considered are those that affect the economic benefits derived from the use of the asset. Customers’ rights to direct the use of the identified asset include the rights to change: • The type of output produced by the asset. • When the output is produced. • Where the output is produced. • Whether the output is produced and the quantity of that output. On the other hand, rights that are limited to maintaining or operating the asset may not grant a right to direct how and for what purpose the asset is used.

10.1.4 Embedded Leases

Often, the assessment of whether a contract is, or contains, a lease will be straightforward. However, the evaluation will be more complicated when an arrangement involves both a service component and a leasing component or when both the customer and the supplier make decisions about the use of the underlying asset. An asset typically is identified by being explicitly specified in a contract. However, an asset also can be identified by being implicitly specified at the time the asset is made available for the customer’s use.

The following decision tree illustrates how to evaluate whether an arrangement is, or contains, a lease:



Example 10-1

Contract Manufacturing Arrangement

Entity A, a pharmaceutical company, enters into an arrangement with a contract manufacturer, Entity B, to purchase a particular type, quality, and quantity of the API needed to manufacture drug compound X. Entity B has only one factory that can meet the requirements of the contract with A, and B is prohibited from supplying A through another factory or third-party suppliers. Entity A has not contracted for substantially all of B's factory's capacity.

The required quantities of API are established in the contract at inception. Entity B makes all of the decisions about the factory's operations, including when to run the factory to satisfy the required quantities and which customer orders to fulfill.

The contract does not contain a lease. The factory is an identified asset because it is implicit that B can fulfill the contract only through the use of the specific factory. However, A does not have the "right to obtain substantially all of the economic benefits from use of [an] identified asset" under the leasing standard since the amount of capacity A has contracted for does not represent substantially all of the factory's capacity. In addition, A does not have the "right to direct the use of the identified asset" under the leasing standard. While A may specify quantities of product, B has the right to direct the factory's use because it can determine when to run the factory and which customer contracts to fulfill. As a result, A does not meet the leasing standard's criterion of directing "how and for what purpose" the factory is being used, and the arrangement does not contain a lease.

In accordance with ASC 842-10-15-2, an entity is required at contract inception to identify whether a contract contains a lease. Not all contracts that contain accounting leases will be labeled as such, and accounting leases may be embedded in larger service arrangements.

Failure to identify accounting leases, including those embedded in service arrangements, could lead to a financial statement error. On the other hand, if a customer concludes that a contract is a service arrangement and that contract does not contain an embedded lease, the customer is not required to reflect the contract on its balance sheet (unless required to do so by other U.S. GAAP).

Example 10-2

Placement of Medical Device With Sale of Consumables

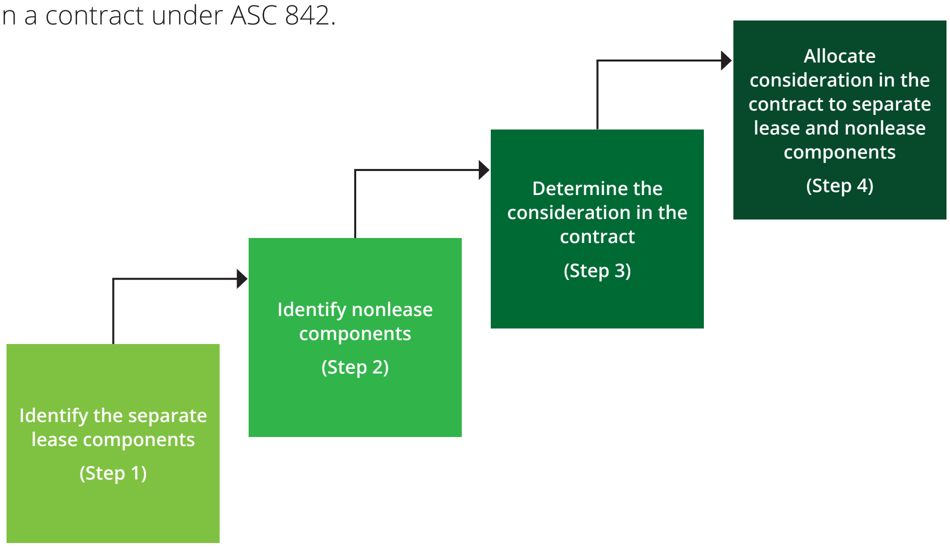
Entity C is a medical device manufacturer that supplies diagnostic kits to customers. The kits can be used only on instruments manufactured by C. Entity C provides its customers with the right to use its instruments at no separate cost to the customer in exchange for a multiyear agreement to purchase annual minimum quantities of diagnostic kits. The term of the agreement generally corresponds to the expected useful life of the instruments. Entity C retains title to the instruments and is permitted to substitute them under the terms of the contract, although historically these instruments have been substituted only when they malfunction since C does not benefit economically from the exercise of its right to substitute the asset.

The multiyear agreement to purchase diagnostic kits contains an embedded lease for the instrument system. The instrument system is an identified asset because it is implicit that C can fulfill the contract only through the customers' use of the specific instruments. Although C has the right to substitute the instruments, the substitution right is not substantive because of the lack of economic benefit from doing so. In addition, customers have the right to control the instruments' use because they have the right to obtain substantially all of the economic benefits from the use of the instruments during the multiyear term of the contract, which corresponds to the useful life of the instruments. Further, customers can make decisions about how and when the instruments are used when the customers perform diagnostic testing procedures.

10.1.5 Components of a Contract

A contract can contain both lease and nonlease components. Generally, the nonlease components are services that the supplier is also performing for the customer. For example, in a single contract, the supplier could be leasing a lab facility and related laboratory equipment to a biotechnology customer while also agreeing to provide ongoing maintenance services for the equipment throughout the period of use. Contracts may contain multiple lease components (e.g., leases of land, buildings, and equipment).

The graphic below outlines steps related to considering how to separate, and allocate consideration to, components in a contract under ASC 842.



Once an entity (a customer or supplier) determines that a contract is, or contains, a lease (i.e., part or all of the contract is a lease), the entity must assess whether the contract contains multiple lease components (i.e., when the contract conveys the rights to use multiple underlying assets). ASC 842-10-15-28(a) and (b) prescribe criteria for identifying whether one lease component is considered separate from other lease components in the contract.

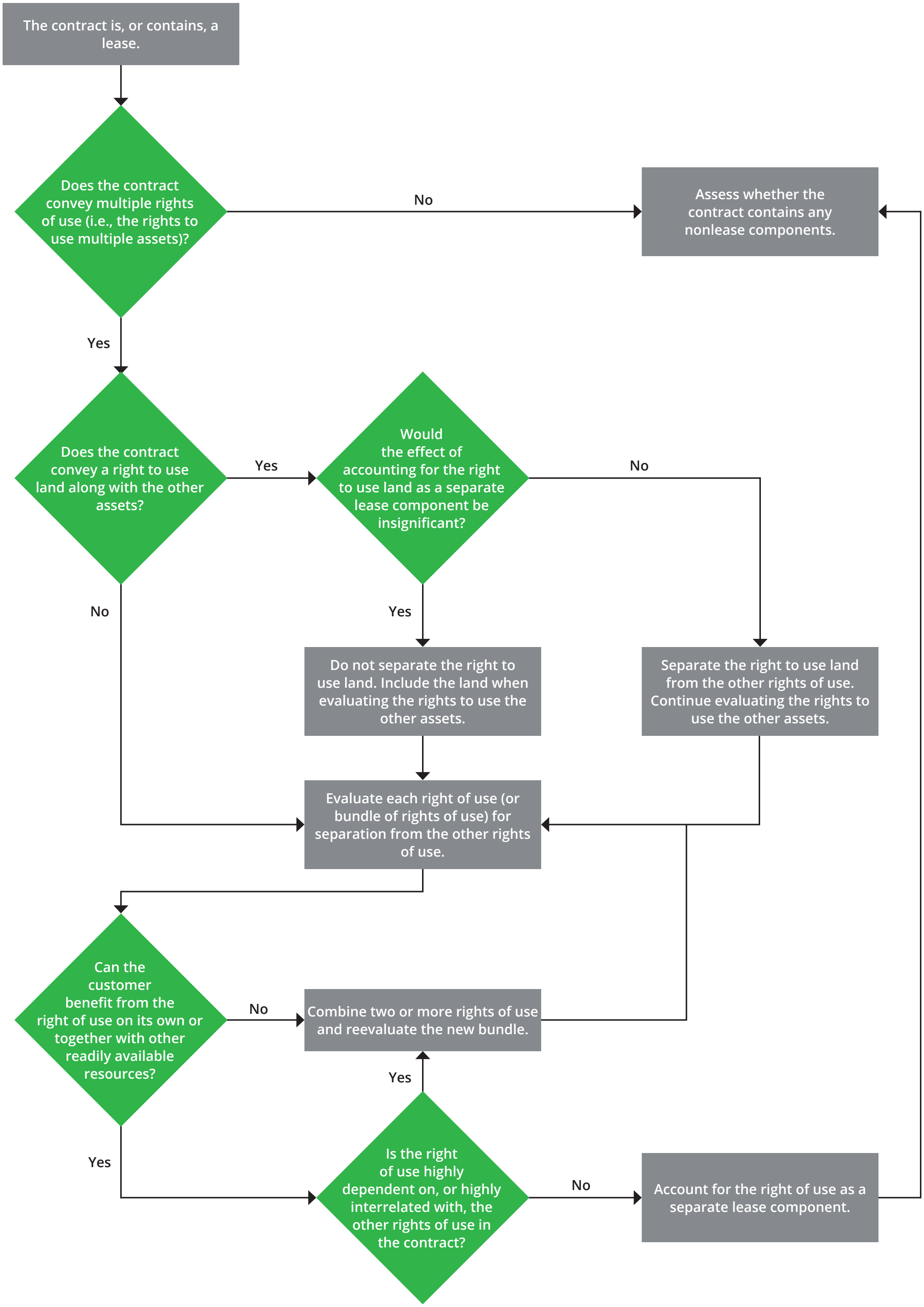
However, land is considered an exception to the guidance in ASC 842-10-15-28. ASC 842-10-15-29 requires an entity to separate a right to use land from the rights to use other underlying assets (e.g., from the right to use a building that sits on top of the land) unless the effect of separating the land is insignificant to the resulting lease accounting.

Connecting the Dots

The leasing standard indicates that it is important for an entity to identify the appropriate unit of account when applying the lessee or lessor accounting model since the unit of account can affect the allocation of consideration to the components in the contract. Paragraph BC145 of ASU 2016-02 states, in part:

> By way of example, regarding allocation, the Board noted that the standalone price (observable or estimated) for a bundled offering (for example, the lease of a data center) may be substantially different from the sum of the standalone prices for separate leases of the items within a bundled offering (for example, the lease of each asset in the data center). Given the substantially different accounting for lease and nonlease components in Topic 842, the allocation of contract consideration carries additional importance as compared with previous GAAP. Consequently, the Board concluded that including separate lease components guidance in Topic 842 will result in more accurate accounting that also is more consistent among entities.

The decision tree on the following page illustrates how an entity might think about the guidance in ASC 842-10-15-28 and 15-29 for each contract containing a lease.


The contract is, or contains, a lease.
Does the contract convey multiple rights of use (i.e., the rights to use multiple assets)?
No
Assess whether the contract contains any nonlease components.
Yes
Does the contract convey a right to use land along with the other assets?
Yes
Would the effect of accounting for the right to use land as a separate lease component be insignificant?
No
No
Yes
Do not separate the right to use land. Include the land when evaluating the rights to use the other assets.
Separate the right to use land from the other rights of use. Continue evaluating the rights to use the other assets.
Evaluate each right of use (or bundle of rights of use) for separation from the other rights of use.
Can the customer benefit from the right of use on its own or together with other readily available resources?
No
Combine two or more rights of use and reevaluate the new bundle.
Yes
Yes
Is the right of use highly dependent on, or highly interrelated with, the other rights of use in the contract?
No
Account for the right of use as a separate lease component.

Once the separate lease components are identified, entities must determine whether there are any nonlease components to be separated. An allocation of contract consideration is required for both lease and nonlease components since they transfer a good or service to the customer. However, allocation of contract consideration does not extend to activities that do not transfer a good or service to the customer, which are referred to as "noncomponents" (e.g., administrative tasks and reimbursement or payment of the lessor's costs).

Understanding the difference between lease components, nonlease components, and noncomponents is critical. The table below outlines these concepts in greater detail.

Lease Component	The right to use an underlying asset is considered a separate lease component if (1) a lessee can benefit from the use of the underlying asset either on its own or with other resources that are readily available and (2) the underlying asset is not highly dependent on or highly interrelated with other assets in the arrangement.
Nonlease Component	An activity that transfers a separate good or service to the customer is a nonlease component. For example, maintenance services consumed by the customer and bundled with the lease component in the contract would be a separate nonlease component because the performance of the maintenance transfers a service to the customer that is separate from the right to use the asset.
Noncomponent	Any activity in a contract that does not transfer a separate good or service to the lessee is neither a lease component nor a nonlease component; therefore, consideration in the contract would not be allocated to such an activity. For example, payments made by the customer for property taxes or insurance that covers the supplier's interests would not represent a component in the contract.

ASC 842 affords lessees a practical expedient related to separating (and allocating consideration to) lease and nonlease components. That is, lessees may elect to account for the nonlease components in a contract as part of the single lease component to which they are related. The practical expedient is an accounting policy election that must be made by class of underlying asset (e.g., vehicles, information technology [IT] equipment — see the Connecting the Dots discussion below).

Accordingly, when a lessee elects the practical expedient, any portion of consideration in the contract that would otherwise be allocated to the nonlease components will instead be accounted for as part of the related lease component for classification, recognition, and measurement purposes. In addition, any payments related to noncomponents would be accounted for as part of the related lease component (i.e., the associated payments would not be allocated between the lease and nonlease components).

Connecting the Dots

ASC 842 provides lessees with two practical expedients that may be elected as an accounting policy by "class of underlying asset":

- ASC 842-10-15-37 allows lessees not to separate lease and nonlease components.
- ASC 842-20-25-2 allows lessees not to recognize lease liabilities and ROU assets for short-term leases (i.e., leases with a term of 12 months or less).

Identify nonlease components

(Step 2)

However, ASC 842 does not address what is meant by the phrase "class of underlying asset." We have received a number of questions about this topic from various stakeholders, and two views have emerged:

- *View 1* — The class of underlying asset is determined on the basis of the physical nature and characteristics of the asset. For example, real estate, manufacturing equipment, and vehicles would all be reasonable classes of underlying assets given their differences in physical nature. Therefore, irrespective of whether there are different types of similar assets (e.g., within the real estate class, there may be retail stores, warehouses, and distribution centers), the class of underlying asset would be limited to the physical nature as described above.
- *View 2* — The class of underlying asset is determined on the basis of the risks associated with the asset. While an asset's physical nature may be similar to that of other assets (e.g., retail stores, warehouses, and distribution centers are all real estate, as discussed above), each has a different purpose and use to the lessee and would therefore have a separate risk profile. Therefore, for example, it could be appropriate for the lessee to disaggregate real estate assets into separate asset classes by "type" of real estate — to the extent that the different types are subject to different risks — when applying the practical expedients in ASC 842-10-15-37 and ASC 842-20-25-2.

To support their position, proponents of View 2 refer to paragraph BC341 of ASU 2016-02, which states:

> The Board decided that a lessor should treat assets subject to operating leases as a major class of depreciable assets, further distinguished by significant class of underlying asset. Accordingly, a lessor should provide the required property, plant, and equipment disclosures for assets subject to operating leases separately from owned assets held and used by the lessor. **In the Board's view, leased assets often are subject to different risks than owned assets that are held and used** (for example, the decrease in the value of the underlying asset in a lease could be due to several factors that are not within the control of the lessor), and, therefore, users will benefit from lessors segregating their disclosures related to assets subject to operating leases from disclosures related to other owned property, plant, and equipment. **The Board further considered that to provide useful information to users, the lessor should disaggregate its disclosures in this regard by significant class of underlying asset subject to lease because the risk related to one class of underlying asset (for example, airplanes) may be very different from another (for example, land or buildings).** [Emphasis added]

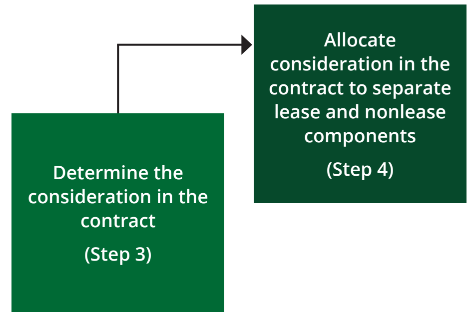
Irrespective of the views noted above, we do not think that it would be appropriate to determine the "class of underlying asset" on the basis of the lease contract with which it is associated. For example, we believe that it would be inappropriate to break real estate assets into different classes on the basis of whether they are related to gross leases or triple net leases. In that situation, the asset underlying the contract could be the same while the contract terms differ. We do not believe that such an approach is consistent with the intent of the guidance in ASC 842-10-15-37 or ASC 842-20-25-2.

In addition to the practical expedient available to lessees, lessors can elect not to separate lease and nonlease components. This election is made by each class of underlying asset and can only be made if certain criteria are met. Specifically, a lessor can elect to combine a lease component with a nonlease component provided that (1) the timing and pattern of transfer for the lease component are the same as those for the nonlease component associated with that lease component and (2) the lease component would be classified as an operating lease if accounted for separately from the nonlease component. See ASU 2018-11 and Section 4.3.3.2 of Deloitte's Roadmap *Leases* for more information.

At this point, entities have identified their separate lease and nonlease components to which consideration in the contract will be allocated. Noncomponents have also been identified to ensure that consideration in the contract is not allocated to them.

Next, entities must:

- Determine the consideration in the contract.
- Allocate the consideration in the contract to the separate lease and nonlease components.



The matrix below summarizes the requirements related to measuring and allocating the consideration in the contract for lessees and lessors.

	Lessee	Lessor
Determining the consideration in the contract	Includes: • Lease payments. • Any other fixed payments. • Any other variable payments based on index or rate.	Includes: • Lessee consideration in the contract (i.e., everything in the column at left). • Estimate of variable consideration (determined under ASC 606) when it is related only to the nonlease component(s).
Allocating the consideration in the contract to lease and nonlease components	When practical expedient is elected, no allocation is performed.	When practical expedient is elected for eligible nonlease components, no allocation is performed.
	When practical expedient is not elected, allocate on the basis of: • Observable stand-alone price, if readily available. • Otherwise, estimated stand-alone price (maximizing use of observable inputs).	When practical expedient is not elected, allocate on the basis of stand-alone selling price in accordance with ASC 606 (see Chapter 7 of Deloitte's Roadmap *Revenue Recognition*).

Example 10-3

Accounting for an Embedded Lease With Lease and Nonlease Components

Entity A, a pharmaceutical company, enters into an arrangement with Entity B, a CMO, to produce a drug substance by using a dedicated production line designed specifically for the exclusive use of A. Assume that key operating decisions are predetermined by A and that A must approve any changes to production plans.

This arrangement is likely to contain a lease accounted for under ASC 842. The production line is an explicitly identified asset in the contract, there are no substitution rights, and A has the right to obtain substantially all of the economic benefit from the use of the identified asset. In addition, A directs the use of the identified asset because B does not have the right to make operating decisions without A's prior approval.

Example 10-3 (continued)

As a result, A should allocate the expected consideration between the leased production line (the lease component) and the services required to produce the drug substance (the nonlease component) on the basis of their relative stand-alone selling prices at the inception of the contract. If the arrangement includes fixed consideration (including minimum monthly volumes at fixed prices), A would record on its balance sheet (1) a lease liability at the present value of the amount of fixed consideration allocated to the lease and (2) a corresponding ROU asset. If the contract contains no minimum volumes, the arrangement would still contain an embedded lease, but the consideration would be 100 percent variable. Because variable consideration is excluded from the measurement of the lease liability, there would be no initial accounting for this agreement. Instead, A would allocate and record a portion of each payment as variable lease expense for the embedded lease component and a portion as the cost of the contract manufacturing. Alternatively, A may elect to use the practical expedient in ASC 842 of not separating the lease component from the nonlease component and accordingly may account for the consideration in the arrangement entirely as lease expense.

In a similar manner, B, the CMO and lessor, may be required to identify two components in this contract: use of the dedicated space (a lease component) and the drug substance output of the contract manufacturing line (a nonlease component).

10.1.5.1 Allocating Consideration in Arrangements Involving the Use of an Asset for "Free"

Vendors in certain industries (e.g., med tech) often provide customers with the right to use, for a specified period, a piece of equipment for no charge ("free equipment") in exchange for exclusive rights to supply related products (i.e., consumables). The equipment typically can be used only to dispense consumables that are sold by the vendor. In many cases, the customer has the right, but not the obligation, to purchase consumables from the vendor at a specified price. These arrangements may be referred to as "free lease" arrangements because they often contain no explicit consideration related to the use of the equipment; rather, the consideration in the contract consists of a charge per unit of consumable purchased by the customer. Examples of such arrangements may include a contract that conveys the use of an X-ray scanner to a hospital (the hospital may purchase contrast dyes only from the vendor).

When a vendor enters into a free lease arrangement, there must be a determination of whether to allocate the consideration in the contract between the use of the equipment (i.e., a lease component) and the purchase of the consumables (i.e., a nonlease component). In general, we would expect the consideration in the contract (even if the consideration is all variable) to be allocated among the contract components. We would not normally expect a vendor to provide equipment to a customer without expecting compensation. This would suggest that some of the per-unit price of the consumables should be allocated to the use of the equipment.

However, in some limited circumstances, allocating 100 percent of the per-unit price to the consumable sales is permitted if the following criteria are met:

- The contract only includes variable payments not based on an index or rate; that is, the contract does not contain any fixed or in-substance fixed payments.
- The consumables are priced at (or below) their stand-alone selling price.
- The equipment is insignificant in the context of the contract.

If the contract contains a fixed or in-substance fixed payment, as described in ASC 842-10-30-5 and ASC 842-10-15-35 (e.g., a minimum commitment to purchase consumables), such amounts must be allocated between the identified equipment in the arrangement and any nonlease components. In these situations, provided that the customer has the right to control the use of the identified equipment, such a contract contains a lease of the equipment. (A lease is defined in ASC 842 as a "contract, or part of a contract, that conveys the right to control the use of identified [PP&E] for a period of time **in exchange for consideration**" [emphasis added].)

The second criterion is designed to identify scenarios in which a vendor has not "marked up" the consumables to compensate itself for providing the customer with use of the equipment. To the extent that the per-unit price is at or below the vendor's stand-alone selling price for the consumables (i.e., the per-unit price is the same as or lower than the per-unit price for a customer that purchases the equipment), this fact constitutes evidence that the vendor is not seeking or receiving incremental compensation for the equipment.

If the first two criteria are met, the vendor should evaluate the equipment's value in relation to the overall combined value of the arrangement (including an estimate of the consumable value by using its best projection of consumables to be purchased over the contract term). The vendor should also consider other relevant factors (qualitative and quantitative) to determine whether the equipment is insignificant in the context of the contract.

The fact that an arrangement satisfies these three criteria may suggest that the vendor has provided the right to use its asset over the term of the contract for no compensation. While future consumable purchases are expected, there are no enforceable rights to require future purchases. Therefore, in a manner consistent with an optional purchase model for a revenue transaction (as described in TRG Agenda Paper 48), those future consumable purchases are not enforceable and do not create additional consideration in the arrangement, and the customer thus obtains use of the vendor's asset without any obligation to make payments. This outcome is consistent with a revenue transaction in which a vendor provides its customer with an up-front deliverable (e.g., a razor) for no consideration and expects (but is not able to require) the customer to make subsequent purchases of consumables (razor blades). In this revenue transaction, the vendor would record no revenue for the up-front deliverable (razor) and would incur a day 1 loss upon the transfer of control of the deliverable (razor) to the customer.

Example 10-4

Vendor L provides Customer H with "free" diagnostic equipment for a stated noncancelable term of five years. The equipment has no use other than in combination with consumables sold by L to produce a testing result. The equipment is explicitly specified in the contract, and H controls the use of the equipment during the five-year contract term through its exclusive use and ability to direct the use of the equipment. Customer H is required to return the equipment to L at the end of the contract term. The contract contains no explicit consideration for the use of the equipment; the consideration consists of a cost per unit of consumable purchased by H.

Throughout the five-year contract term, H has the right, but not the obligation, to purchase consumables from L to use in operating the equipment. The contract does not contain any minimum purchase commitments related to the consumables. Customer H may only use the consumables with the equipment provided by L and may not use a third-party vendor's consumables with the equipment.

Vendor L has determined that the stand-alone selling price for the use of the equipment over a five-year term is $200,000.

Example 10-4 (continued)

Scenario 1 (Before the Adoption of ASU 2021-05)

At contract inception, L estimates that H will purchase 100,000 consumables during the five-year contract term. The stand-alone selling price of consumables is $6 per unit and the selling price within the contract is $7.50 per unit, yielding an estimated $750,000 of contract consideration.

On the basis of these additional facts, the contractual price of consumables (i.e., $7.50 per unit) is higher than the stand-alone selling price of the consumables (i.e., $6 per unit). The higher contractual price is most likely established to compensate L for the use of the equipment. Even though there are no fixed or in-substance fixed payments, since the price of the consumables is higher than the stand-alone selling price, L would conclude that this contract includes both a lease component and a nonlease component.

Vendor L would be required to allocate consideration between the use of the equipment (a lease) and the sale of consumables. Vendor L will allocate the consideration between the equipment and the estimated future consumable purchases on the basis of their respective stand-alone selling prices, as determined at lease inception. The consideration in the contract is allocated as follows:

Component	Consideration in the Contract	Stand-Alone Selling Price	Allocation Percentage	Allocated Consideration
Five-year lease of equipment (i.e., variable lease income)	$ —	$ 200,000	25%	$ 187,500 ($1.88 per consumable)
Consumables (i.e., revenue)	750,000	600,000	75%	562,500 ($5.63 per consumable)
Total	$ 750,000	$ 800,000	100%	$ 750,000

Since consideration must be allocated to the use of the equipment, this component of the arrangement will generally meet the definition of a lease (i.e., the right to control the use of identified PP&E for a period of time in exchange for consideration). For each consumable purchased by H, L will recognize $1.88 as variable lease income and $5.63 as revenue.

This scenario resulted in a conclusion that a lease exists because the contractual price of consumables is higher than the stand-alone selling price. However, even if this were not the case, because the equipment value is quantitatively assessed as 25 percent of the total contract value, a lease component would most likely still be identified given the significance of the equipment to the overall contract.

Depending on the life of the equipment compared with the contract term (i.e., if the contract term is greater than 75 percent of the useful life of the equipment), these arrangements may qualify as sales-type leases and could lead to commencement losses because of their dependence on variable consideration.

With respect to operating leases of equipment, note that vendors will generally not qualify to use the lessor practical expedient related to not separating the lease (i.e., equipment) and nonlease (i.e., consumables) components in the contract because the transfer of consumables occurs at a point in time whereas the transfer of the leased equipment is over time.

Scenario 2 (After the Adoption of ASU 2021-05)

Assume the same facts as Scenario 1. The contractual price of consumables (i.e., $7.50 per unit) is higher than the stand-alone selling price of the consumables (i.e., $6 per unit). The higher contractual price is most likely established to compensate L for the use of the equipment. Even though there are no fixed or in-substance fixed payments, since the price of the consumables is higher than the stand-alone selling price, L would conclude that this contract includes both a lease component and a nonlease component.

Example 10-4 (continued)

Vendor L would be required to allocate consideration between the use of the equipment (a lease) and the sale of consumables. Vendor L will allocate the consideration between the equipment and the estimated future consumable purchases on the basis of their respective stand-alone selling prices, as determined at lease inception. The consideration in the contract is allocated as follows:

Component	Consideration in the Contract	Stand-Alone Selling Price	Allocation Percentage	Allocated Consideration
Five-year lease of equipment (i.e., variable lease income)	$ —	$ 200,000	25%	$ 187,500
				($1.88 per consumable)
Consumables (i.e., revenue)	750,000	600,000	75%	562,500
				($5.63 per consumable)
Total	$ 750,000	$ 800,000	100%	$ 750,000

Since consideration must be allocated to the use of the equipment, this component of the arrangement will generally meet the definition of a lease (i.e., the right to control the use of identified PP&E for a period of time in exchange for consideration). For each consumable purchased by H, L will recognize $1.88 as variable lease income and $5.63 as revenue.

This scenario resulted in a conclusion that a lease exists because the contractual price of consumables is higher than the stand-alone selling price. However, even if this were not the case, because the equipment value is quantitatively assessed as 25 percent of the total contract value, a lease component would most likely still be identified given the significance of the equipment to the overall contract.

Before the adoption of ASU 2021-05, the arrangement in the scenario described above may qualify as a sales-type lease depending on the life of the equipment compared with the contract term (i.e., if the contract term is greater than 75 percent of the useful life of the equipment). After the adoption of ASU 2021-05, however, if treating the lease as a sales-type lease would result in the recognition of a selling loss at lease commencement, the lease would be classified as an operating lease in accordance with ASC 842-10-25-3A because of the inclusion of variable consideration. (See Connecting the Dots in Section 9.3.7.1.2 of Deloitte's Roadmap *Leases* for more information about commencement losses related to sales-type leases.)

Example 10-5

Assume the same initial facts as in the example above. At contract inception, Vendor L estimates that Customer H will purchase 450,000 consumables during the five-year contract term. The stand-alone selling price of consumables is $7.50 per unit, as evidenced by separate observable sales of consumables within contracts in which L sells the equipment to customers. Use of the contractual price of $7.50 per unit yields an estimated $3.375 million of contract consideration.

First, L observes that the contract does not include any fixed or in-substance fixed payments throughout the contract term. Then, L considers that its business model is to provide the equipment for free to drive consumable sales, which is corroborated by the fact that the contractual price of consumables is identical to the stand-alone selling price of the consumables (i.e., a customer that purchases the equipment would pay the same price as a customer that signs this contract); L's primary objective is to sell consumables, not to sell the insignificant equipment.

Example 10-5 (continued)

The table below illustrates how L may assess the relative value within the contract and how it would allocate the consideration to the potential components.

Component	Stand-Alone Selling Price	Allocation Percentage
Equipment	$ 200,000	5.6%
Consumables	3,375,000	94.4%
Total	$ 3,575,000	100%

On the basis of this calculation, L concludes that the equipment value is approximately 5.6 percent of the total contract value. Upon considering this quantitative factor as well as other qualitative factors, L determines that the equipment is insignificant to the overall contract.

Accordingly, in this scenario, it may be acceptable for L to conclude that this contract does not include a lease since L has determined that **no** consideration is provided for the use of the equipment. (A lease is defined in ASC 842 as a "contract, or part of a contract, that conveys the right to control the use of identified [PP&E] for a period of time **in exchange for consideration**" [emphasis added].) As a result, 100 percent of the consideration would be allocated to the sale of the consumables (i.e., revenue). Compared with the conclusion reached in Scenarios 1 and 2 of Example 10-4 above, this conclusion does not result in a timing difference for revenue recognition purposes but could result in a different presentation and disclosure outcome: revenue from contracts with customers and variable lease income would be presented in Scenarios 1 and 2, whereas only revenue from contracts with customers would be presented in this example.

In addition, L should assess whether H obtains control of the equipment (not just the right to use it for five years). If control has been transferred, L would incur a day 1 loss upon delivery of the equipment to H, in a manner similar to the above example involving razors and razor blades.

Conversely, if L determines that H did not obtain control of the equipment, L would continue to recognize the equipment as PP&E subject to the guidance in ASC 360 on subsequent measurement (e.g., depreciation and impairment). Generally, control of the equipment is transferred to the customer when the term of the arrangement constitutes the major part of the remaining useful life of the equipment. However, if the vendor has a right to reclaim the equipment during the term of the arrangement without the customer's permission (e.g., in cases in which the customer is not purchasing as many consumables as expected), this reclamation right may indicate that control of the equipment has not been transferred.

10.1.6 Lease Classification — Lessee

Under ASC 842, at lease commencement, a lease is classified as a finance lease (for a lessee) or a sales-type lease (for a lessor) if any of the following criteria are met:

- "The lease transfers ownership of the underlying asset to the lessee by the end of the lease term."
- "The lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise."
- "The lease term is for the major part of the remaining economic life of the underlying asset."
- "The present value of the sum of the lease payments and any residual value guaranteed by the lessee . . . equals or exceeds substantially all of the fair value of the underlying asset."
- "The underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term."

Finance leases are accounted for in a manner similar to how entities account for a financed purchase arrangement. The lessee recognizes interest expense and amortization of the ROU asset, which result in a greater expense in the early years of the lease than in the later years of the lease. The single lease cost related to an operating lease is recognized on a straight-line basis over the lease term unless another systematic and rational basis is more representative of the pattern in which benefit is expected to be derived from the right to use the underlying asset. Thus, the amortization of an ROU asset related to an operating lease takes into account the interest on the liability so that the expense amount remains constant. That is, the amortization of the ROU asset will increase or decrease proportionally to the change in interest expense on the liability to maintain a straight-line expense throughout the term of the lease. For both types of leases, the lessee recognizes an ROU asset for its interest in the underlying asset and a corresponding lease liability.

Connecting the Dots

While many aspects of the lease classification criteria under ASC 842 are consistent with legacy lease accounting guidance, bright-line tests (i.e., whether the lease term is for 75 percent or more of the remaining economic life of the asset or whether the present value of the lease payments, including any guaranteed residual value, is at least 90 percent of the fair value of the underlying asset) are noticeably absent. However, ASC 842-10-55-2 states that these tests are "one reasonable approach to assessing the criteria." On the basis of this implementation guidance, entities often can use bright-line thresholds as policy elections when evaluating the classification of a lease arrangement under the leasing standard. However, as with all policy elections, it is important for entities to consider the full range of impact and the need for policy elections to be consistently applied.

10.1.7 Lessor Accounting

After proposing different amendments to lessor accounting, the FASB ultimately decided to make only minor modifications to the lessor model. The most significant changes (1) align the profit recognition requirements under the lessor model with the revenue standard and (2) amend the lease classification criteria for a lessor to make them consistent with those for a lessee. Accordingly, the leasing standard requires a lessor to use the classification criteria discussed above to classify a lease, at its commencement, as a sales-type, direct financing, or operating lease.

Regarding leveraged leases (i.e., leases that met the criteria in ASC 840-10-25-43(c)), paragraph BC397 of ASU 2016-02 explains that the FASB decided to grandfather in existing leveraged leases given that "there would be significant complexities relating to unwinding existing leveraged leases" during transition. Therefore, a lessor must continue to apply the accounting in ASC 840 for such a lease (as carried forward in ASC 842) and classify the lease as a leveraged lease provided that it enters into the lease before the effective date of ASC 842. Otherwise, leveraged lease accounting is eliminated as of the date of adoption.

While the FASB's goal was to align lessor accounting with the revenue guidance in ASC 606, an important distinction between the two may affect lessors in the life sciences industry. Under ASC 606, variable payments are estimated and included in the transaction price subject to a constraint. By contrast, under ASC 842, variable lease payments not linked to an index or rate are generally excluded from the determination of a lessor's lease receivable. Accordingly, under the guidance in ASC 842 as originally issued, sales-type or direct financing leases that have a significant variable lease payment component may result in recognition of a loss at commencement because the measurement of the lease receivable plus the unguaranteed residual asset is less than the net carrying value of the underlying asset.

For example, it is not uncommon for a hospital to contract with a medical device owner for the use of specific medical equipment for a major part of the economic life of the equipment. This type of arrangement is often priced in such a way that the consideration is based entirely on the hospital's ongoing purchase of "consumables," which allow the equipment to function as designed, and may have no minimum volume requirement. The medical device owner is willing to accept variable consideration in the arrangement because demand for the associated health care services suggests that a sufficient volume of consumables will be purchased by the hospital over the term of the contract to make the arrangement profitable. See Section 10.1.5.1 for more accounting considerations related to this type of arrangement.

In July 2021, the FASB issued ASU 2021-05, which requires a lessor to classify a lease with variable lease payments that do not depend on an index or rate as an operating lease on the commencement date of the lease if specified criteria are met. The Board issued the ASU in response to stakeholder feedback indicating that the accounting for such a lease was not faithfully representing the underlying economics of the transaction at lease commencement or over the lease term. When a lease is classified as operating, the lessor does not recognize a net investment in the lease and does not derecognize the underlying asset; therefore, the lessor does not recognize selling profit or loss.

10.1.8 Real Estate Rationalization

The COVID-19 pandemic ignited a shift in how entities in almost every industry sector are doing business. Many entities are reevaluating where their employees conduct their required business activities and to what extent they will rely on the use of brick-and-mortar real estate assets on a go-forward basis. Specifically, many entities initiated a real estate rationalization program to reevaluate their organization-wide real estate footprint. The goal of initiating such programs may be for entities to rightsize their real estate portfolios to manage costs while adequately supporting their evolving business needs.

We have also observed an increase in entities abandoning properties, subleasing space they are no longer using, or modifying existing leases to change the amount of space or the lease term. Further, as a financing method to improve their liquidity, entities are increasingly entering into sale-and-leaseback transactions involving real estate. As a result of these real estate rationalization efforts, entities are also more frequently evaluating leases for impairment. For more information about these topics, see Sections 10.1.9 through 10.1.12 below.

10.1.9 Lease Modifications

A lease modification is any change to the contractual terms and conditions of a lease. Under the leasing standard, a lease modification is accounted for as follows:

- A lessee or lessor accounts for a lease modification as a separate contract (i.e., separate from the original lease) when the modification (1) grants the lessee an additional ROU asset and (2) the price of the additional ROU asset is commensurate with its stand-alone price.
- A lessee accounts for a lease modification that is not a separate contract by using the discount rate as of the modification's effective date to adjust the lease liability and ROU asset for the change in the lease payments. The modification may result in a gain or loss if the modification results in a full or partial termination of an existing lease.
- A lessor accounts for a lease modification in a manner that is generally consistent with the contract modification guidance in ASC 606.

Example 10-6

Lease Modifications

Scenario 1 — Modification Resulting in a Separate Contract

Company A, a pharmaceutical entity (the lessee), enters into an arrangement to lease 15,000 square feet of office space in a complex for 20 years. At the beginning of year 10, A and the lessor agree to amend the original lease to include an additional 5,000 square feet of space adjacent to the existing space currently being leased when the current tenant vacates the property in 18 months. The increase in lease consideration as a result of the amendment is commensurate with the market rate for the additional 5,000 square feet of space in the complex. Company A would account for this modification (i.e., the lease of the additional 5,000 square feet) as a separate contract because the modification provides A with a new ROU asset at a price that reflects that asset's stand-alone price. While A would be required to disclose certain information about the lease modification, it would not be required to separately record any amounts in its statement of financial position until the separate lease's commencement date (i.e., 18 months from entering into the modification).

Scenario 2 — Modification Not Resulting in a Separate Contract

Company A, a pharmaceutical entity (the lessee), enters into an arrangement to lease 15,000 square feet of office space in a complex for 20 years. At the end of year 10, A and the lessor agree to amend the original lease by reducing the annual rental payments from $60,000 to $50,000 for the remaining 10 years of the agreement. Because the modification results in a change only to the lease consideration (i.e., the modification does not result in an additional ROU asset), A would remeasure its lease liability to reflect (1) a 10-year lease term, (2) annual lease payments of $50,000, and (3) A's incremental borrowing rate (or the rate the lessor charges the lessee if such rate is readily determinable) as of the modification's effective date. Company A would recognize the difference between the new and old lease liabilities as an adjustment to the ROU asset. Since the modification does not result in a full or partial termination of the lease, there is no gain or loss on the modification.

10.1.10 Subleases

When the original lessee subleases the leased asset to an unrelated third party, the lessee becomes the intermediate lessor in the sublease arrangement. As the intermediate lessor of a leased asset, the entity would determine the classification of the sublease independently from its determination of the classification of the original lease (i.e., the head lease). Under the leasing standard, the intermediate lessor would classify the sublease on the basis of the underlying asset (i.e., it would assess the term of the sublease relative to the remaining economic life of the underlying asset). When evaluating lease classification and measuring the net investment in a sublease classified as a sales-type or direct financing lease, the original lessee (as a sublessor) should use the rate implicit in the lease if it is determinable. If the implicit rate is not determinable, the original lessee would use the discount rate that it used to determine the classification of the original lease.

In addition, offsetting is generally prohibited on the balance sheet unless the arrangement meets the offsetting requirements of ASC 210-20. However, it may be appropriate in certain instances to net sublease activity in the income statement. See Section 14.3.1.2.1 of Deloitte's Roadmap *Leases* for additional considerations related to when net presentation in the income statement may be appropriate.

Example 10-7

Accounting for a Sublease Under ASC 842

As a lessee, Company A, a life sciences entity, enters into a building lease with a 30-year term. The building has an estimated economic life of 40 years. At the end of year 5, A enters into an agreement with Company B, a generics and consumer health entity, under which A subleases the building to B for 20 years. There is no residual value guarantee, and A determines that the present value of the sublease payments received from B does not represent substantially all of the fair value of the building.

As the lessor in its agreement with B, A would account for the lease to B (the sublease) as an operating lease because (1) the term of the sublease is not for a major part of the remaining life of the underlying asset of the sublease (i.e., the sublease term of 20 years represents only 57 percent of the remaining 35-year life of the building) and (2) A has concluded that no other classification criteria would result in the transfer of control of the underlying asset.

10.1.11 Sale-and-Leaseback Transactions

The seller-lessee in a sale-and-leaseback transaction must evaluate the transfer of the underlying asset (sale) under the requirements of ASC 606 to determine whether the transfer qualifies as a sale (i.e., whether control has been transferred to the customer). The existence of a leaseback by itself would not preclude the transaction from qualifying as a sale (i.e., it would not indicate that control has not been transferred) unless the leaseback is classified as a finance lease. In addition, if the arrangement includes an option for the seller-lessee to repurchase the asset, the transaction would not qualify as a sale unless both of the following criteria are met:

- The option is priced at the fair value of the asset on the date of exercise.
- There are alternative assets that are substantially the same as the transferred asset and readily available in the marketplace.

If the transaction does not qualify as a sale, the seller-lessee and buyer-lessor would account for the transaction as a financing arrangement (i.e., the buyer-lessor would account for its payment as a financial asset and the seller-lessee would record a financial liability).

If the transaction qualifies as a sale, the leaseback is accounted for in the same manner as all other leases (i.e., the seller-lessee and buyer-lessor would account for the leaseback under the guidance in ASC 842.

Transactions in which a lessee controls an underlying asset before the commencement date of the lease are within the scope of the sale-and-leaseback guidance in ASC 842-40. These transactions include transactions in which the lessee is involved with an asset before that asset is transferred to the lessor and transactions in which the lessee is involved with the construction of the asset (e.g., build-to-suit arrangements). For further discussion of these transactions, see Chapter 11 of Deloitte's Roadmap *Leases*.

Sale-and-leaseback transactions involving real estate that include a repurchase option will not meet the criteria of a sale under ASC 606 regardless of whether the repurchase option is priced at fair value. During the FASB's redeliberation on ASU 2016-02, the Board noted that sale-and-leaseback transactions involving real estate that include a repurchase option would not meet the second criterion in ASC 842-40-25-3. Paragraph BC352(c) of ASU 2016-02 states, in part:

> Board members generally observed that real estate assets would not meet [the] criterion [in ASC 842-40-25-3(b)]. This is because real estate is, by nature, "unique" (that is, no two pieces of land occupy the same space on this planet) such that no other similar real estate asset is "substantially the same."

Therefore, regardless of whether the repurchase option is priced at fair value, the unique nature of real estate would prevent a sale-and-leaseback transaction involving real estate that includes a repurchase option from satisfying the second criterion in ASC 842-40-25-3 since there would be no alternative asset that is substantially the same as the one being leased. Accordingly, in a manner similar to legacy U.S. GAAP, the leasing standard would preclude sale-and-leaseback accounting for transactions involving any repurchase options on real estate.

10.1.12 Impairment and Abandonment

The ROU assets recorded on a lessee's balance sheet under ASC 842 are subject to the ASC 360-10 impairment guidance applicable to long-lived assets. When events or changes in circumstances indicate that the carrying amount of the asset group may not be recoverable (i.e., impairment indicators exist), the asset group should be tested to determine whether an impairment exists. The decision to change the use of a property subject to a lease could be an impairment indicator. See Section 8.4.4 of Deloitte's Roadmap *Leases* for more information about the two-step impairment test.

Although the existence of an impairment indicator would not itself be a reason for a lessee to reevaluate the lease term for accounting purposes, an entity should consider whether any of the reassessment events in ASC 842-10-35-1 have occurred simultaneously with the impairment indicator. See Example 5-10 in Section 5.4.1.2 of Deloitte's Roadmap *Leases* for further discussion of the relationship between these concepts.

The guidance in ASC 360-10 on accounting for abandoned long-lived assets also applies to ROU assets. In the context of a real estate lease, when a lessee decides that it will no longer need a property to support its business requirements but still has a contractual obligation under the underlying lease, the lessee needs to evaluate whether the ROU asset has been or will be abandoned. Abandonment accounting only applies when the underlying property subject to a lease is no longer used for **any** business purposes, including storage. If the lessee intends to use the space at a future time or retains the **intent** and **ability** to sublease the property, abandonment accounting would be inappropriate.

10.1.13 Materiality Threshold

When applying the leasing standard's lessee accounting guidance, life sciences companies are likely to consider a materiality threshold, especially for high-volume, low-value leased assets (e.g., laptops). As discussed further in Section 2.2.5.2 of Deloitte's Roadmap *Leases*, ASC 842 does not contain a "small-ticket item" exception similar to that in IFRS 16. ASU 2016-02 indicates that a lessee can use capitalization and materiality policies when evaluating the requirement to recognize, on the balance sheet, leases that otherwise must be recognized under ASC 842, thereby reducing the cost of applying the standard. Specifically, paragraph BC122 of ASU 2016-02 states, in part:

> [E]ntities will likely be able to adopt reasonable capitalization thresholds below which lease assets and lease liabilities are not recognized, which should reduce the costs of applying the guidance. An entity's practice in this regard may be consistent with many entities' accounting policies in other areas of GAAP (for example, in capitalizing purchases of property, plant, and equipment).

One reasonable approach to developing a capitalization threshold for leases is to use the **lesser** of the following:

- A capitalization threshold for PP&E, including ROU assets (i.e., the threshold takes into account the effect of leased assets determined in accordance with ASU 2016-02).
- A recognition threshold for liabilities that takes into account the effect of lease liabilities determined in accordance with the ASU.

Another reasonable approach to developing a capitalization threshold for leases is to record all lease liabilities but to subject the related ROU assets to such a threshold. Under this approach, if an ROU asset is below the established capitalization threshold, it would immediately be recognized as an expense. In subsequent periods, entities would amortize the lease liability by using the effective interest method, under which a portion of the periodic lease payments would reduce the liability and the remainder would be recognized as interest expense.

10.1.14 Application of Judgment and Estimation

Entities must use judgment and make estimates under a number of ASC 842's lease accounting requirements. Judgment is often required in the assessment of a lease's term, which would affect whether the lease qualifies for the short-term exemption and therefore for off-balance-sheet treatment. In addition, since ASC 842 requires almost all leases to be recognized on the balance sheet, judgment in distinguishing between leases and services is more critical under the leasing standard than it was under legacy guidance.

10.1.14.1 Discount Rates

Entities need to recognize ROU assets and lease obligations by using an appropriate discount rate. Compliance with this requirement may be difficult for entities with a significant number of leases since they will need to identify the appropriate incremental borrowing rate for each lease on the basis of factors associated with the underlying lease terms (e.g., lease tenor, asset type, residual value guarantees). That is, entities are not permitted to use the same discount rate for all of their leases unless the leased assets and related terms are similar.

Additional considerations include:

- *Secured versus unsecured rate* — The definition of the incremental borrowing rate under ASC 842 requires lessees to obtain a collateralized or secured borrowing rate. Unsecured rates are likely to be higher and, therefore, to result in a lower lease liability. If a lessee does not borrow on a secured basis, it will most likely need to make adjustments to its unsecured borrowing rates to reflect a rate of a secured borrowing.
- *Parent versus subsidiary rate* — Sometimes it may be appropriate for a subsidiary to use an incremental borrowing rate other than its own. This will depend on the nature of the lease negotiations and the resulting terms and conditions (e.g., a consolidated group with a centralized treasury function that negotiates on behalf of all of its subsidiaries to benefit from its superior credit).
- *Leases denominated in a foreign currency* — When determining an incremental borrowing rate for a lease denominated in a foreign currency, entities should use assumptions that are consistent with a rate that the entities would obtain to borrow in the same currency in which the lease is denominated. The incremental borrowing rate should still reflect a collateralized rate in the relevant foreign environment.
- *Developing a method* — Life sciences entities should define a method for calculating the incremental borrowing rate that is auditable and supportable at transition and on an ongoing basis.

10.1.15 Income Taxes

A lease's classification for accounting purposes does not affect its classification for tax purposes. A life sciences entity will therefore continue to be required to determine the tax classification of a lease under the applicable tax laws. While the classification may be similar for either purpose, the differences in tax and accounting principles and guidance often result in book/tax differences. Thus, an entity needs to have a process to account for these differences.

10.2 Amendments to the Leasing Standard

Since the issuance of ASU 2016-02, the FASB has released additional ASUs addressing implementation challenges raised by stakeholders. Given the far-reaching impact of ASC 842 on many industries, the level of implementation challenges raised has not been surprising. We encourage stakeholders to continue to monitor activity at the FASB, SEC, and other standard setters or regulators for any relevant developments or interpretations.

ASUs issued to date that amend certain aspects of ASC 842 are broadly applicable to the life sciences industry and include the following:

- *ASU 2018-10 on improvements to ASC 842* — In July 2018, the FASB issued ASU 2018-10, which makes 16 narrow-scope amendments (i.e., minor changes and clarifications) to certain aspects of ASC 842.
- *ASU 2018-11 on targeted improvements to ASC 842* — In July 2018, the FASB issued ASU 2018-11 to provide entities with relief from the costs of implementing certain aspects of the leasing standard. Specifically, under the amendments in ASU 2018-11:
    - Entities may elect not to recast the comparative periods presented when transitioning to ASC 842.
    - Lessors may elect not to separate lease and nonlease components when certain conditions are met.
- *ASU 2019-01 on Codification improvements to ASC 842* — In March 2019, the FASB issued ASU 2019-01 to amend certain guidance in ASC 842 in response to feedback from stakeholders. The ASU includes:
    - Guidance on determining the fair value of the underlying asset for lessors other than manufacturers or dealers that aligns with certain legacy guidance in ASC 840.
    - A clarifying amendment that exempts lessees and lessors from providing certain interim disclosures in the fiscal year in which they adopt the leasing standard.
- *ASU 2019-10 and ASU 2020-05 on effective dates of ASC 842 (and those of other Codification topics)* — In November 2019 and June 2020, the FASB issued ASU 2019-10 and ASU 2020-05, respectively, to change, among other effective dates, those of ASC 842 for non-PBEs to fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. At the 2019 AICPA Conference on Current SEC and PCAOB Developments, the SEC staff announced that it would not object if specified PBEs adopt ASC 842 by using ASU 2019-10's timelines that apply to non-PBEs (the "SEC staff position").
- *ASU 2020-02 on an amendment to the SEC paragraph in ASC 842 (and the addition of an SEC paragraph in ASC 326)* — In February 2020, the FASB issued ASU 2020-02 to codify, among other SEC staff guidance, the SEC staff position permitting specified PBEs to use the non-PBE effective dates of ASC 842 provided for in ASU 2019-10. ASU 2020-02 codifies the SEC staff position by adding a note to ASC 842-10-S65-1.

- *ASU 2021-05 on lessor's accounting for certain leases with variable lease payments* — In July 2021, the FASB issued ASU 2021-05, which requires a lessor to classify a lease with variable lease payments that do not depend on an index or rate as an operating lease on the commencement date if specified criteria are met. For an illustration of the allocation of consideration in an arrangement involving the use of an asset for "free" before and after the adoption of ASU 2021-05, see Example 10-4.
- *ASU 2021-09 on the discount rate for lessees that are not PBEs* — In November 2021, the FASB issued ASU 2021-09, which allows lessees that are not PBEs to make an accounting policy election by class of underlying asset, rather than on an entity-wide basis, to use a risk-free rate as the discount rate when measuring and classifying leases.
- *ASU 2023-01 on common-control arrangements* — This ASU is discussed in greater detail below.

For a complete list of ASUs issued to amend and clarify the guidance in ASC 842, see Section 17.3.1 of Deloitte's Roadmap *Leases*.

10.2.1 ASU 2023-01 on Common-Control Arrangements

10.2.1.1 Background and Key Provisions

In March 2023, the FASB issued ASU 2023-01, which amends certain provisions of ASC 842 that apply to arrangements between related parties under common control. Specifically, the ASU:

- Offers private companies, as well as NFPs that are not conduit bond obligors, a practical expedient that gives them the option of using the written terms and conditions of a common-control arrangement when determining whether a lease exists and the subsequent accounting for the lease, including the lease's classification.
- Amends the accounting for leasehold improvements in common-control arrangements for all entities.

10.2.1.1.1 Practical Expedient That Allows the Evaluation of Written Terms and Conditions of a Common-Control Arrangement

ASC 842 requires entities to determine whether a related-party arrangement between entities under common control is a lease on the basis of the legally enforceable terms and conditions of the arrangement. The accounting for a lease depends on the enforceable rights and obligations of each party as a result of the contract. This principle applies irrespective of whether such rights or obligations are included in the contract or explicitly or implicitly provided outside of the contract (i.e., there may be enforceable rights or obligations that extend beyond the written lease contract).

As part of the FASB's postimplementation review of ASC 842, private companies asserted that this requirement creates unnecessary cost and complexity for financial statement preparers, since the terms and conditions of such common-control lease arrangements may lack sufficient details, may be uneconomic, or may be changed without approval, given that one party in the common-control group generally controls the arrangement. Therefore, stakeholders have indicated that it is challenging to determine the legally enforceable terms and conditions of these arrangements and that legal counsel may need to be involved in making this determination, thereby incurring additional cost.

In response to that feedback, ASU 2023-01 provides an optional practical expedient under which private companies, as well as NFPs that are not conduit bond obligors, can use the written terms and conditions of an arrangement between entities under common control to determine (1) whether a lease exists and (2) the subsequent accounting for (and classification of) the lease. This practical expedient can be applied on an arrangement-by-arrangement basis, and an entity is not required to consider the legal enforceability of such written terms and conditions. However, if no written terms and conditions of an arrangement between entities under common control exist, an entity is not allowed to elect the practical expedient and is required to apply ASC 842 in a manner consistent with how it is applied to other arrangements.

10.2.1.1.2 Accounting for Leasehold Improvements in Common-Control Arrangements

Under ASC 842, a lessee is generally required to amortize leasehold improvements that it owns over the shorter of the useful life of those improvements or the lease term. As part of the FASB's postimplementation review of ASC 842, private-company stakeholders have noted that in a lease arrangement between entities under common control, the amortization requirements of ASC 842 are inconsistent with the underlying economics of the arrangement since (1) the lessee may continue to control the use of the underlying asset after the lease term and (2) another party in the common-control group may benefit from the leasehold improvements after the lessee no longer controls the use of the underlying asset.

In response to that feedback, ASU 2023-01 requires a lessee in a common-control lease arrangement to amortize leasehold improvements that it owns over the improvements' useful life to the common-control group, regardless of the lease term, if the lessee continues to control the use of the underlying asset through a lease. This amendment applies to all entities.

In situations in which a lessee obtains control of an underlying asset through a lease with an unrelated party not under common control and subsequently subleases the asset to an entity under common control, the sublessee would generally amortize the leasehold improvements over a period that does not exceed the term of the lease between the lessee/intermediate lessor and the unrelated party. However, if the lease between the lessee/intermediate lessor and the unrelated party contains an option to purchase the underlying asset and the lessee/intermediate lessor is reasonably certain to exercise that option, the leasehold improvements should be amortized over the useful life to the common-control group.

Further, a lessee that no longer controls the use of the underlying asset will account for the transfer of the underlying asset as an adjustment to equity (i.e., as with a transfer of assets between entities under common control).

10.2.1.2 Effective Date

ASU 2023-01 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted in any annual or interim period as of the beginning of the related fiscal year.

Entities have the option of using one of the following adoption methods:

- Prospective application to all new leasehold improvements recognized on or after the date on which the entity first applies the amendments in ASU 2023-01.
- Prospective application to all new and existing leasehold improvements recognized on or after the date on which the entity first applies the amendments in ASU 2023-01, with any remaining balance of leasehold improvements amortized over their remaining useful life to the common-control group determined as of that date.
- Retrospective application to the beginning of the period in which an entity first applied ASC 842, with any leasehold improvements that otherwise would not have been amortized or impaired recognized through a cumulative-effect adjustment to opening retained earnings at the beginning of the earliest period presented in accordance with ASC 842.

10.3 SEC Comment Letter Themes Related to Leases

Although relatively few SEC staff comments on the application of ASC 842 have been issued thus far, some observations in comments related to its application have emerged. For example, registrants have received comments on (1) how ASC 842 applies or does not apply in certain arrangements and (2) the discount rate used to calculate the amount of the lease liability and corresponding ROU asset. Other topics addressed in SEC staff comments on ASC 842 include, but are not limited to, the nature of expenses treated as initial direct costs; the determination of lease classification; accounting for leasehold improvements, including amortization; and impairment considerations related to ROU assets. Given the relatively low volume of SEC staff comments related to ASC 842 that have been issued thus far, registrants should continue monitoring staff comments to identify any new comments or trends related to the leasing standard that may emerge in the future.

For more information about SEC comment letter themes that are relevant to life sciences companies, see Deloitte's Roadmap *SEC Comment Letter Considerations, Including Industry Insights*.

Appendix B — Titles of Standards and Other Literature

AICPA Literature

Accounting and Valuation Guides

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

Clarified Statements on Auditing Standards

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items"

AU-C Section 620, "Using the Work of an Auditor's Specialist"

FASB Literature

ASC Topics

ASC 105, *Generally Accepted Accounting Principles*

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 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 440, *Commitments*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

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 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 712, *Compensation — Nonretirement Postemployment Benefits*

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 832, *Government Assistance*

ASC 835, *Interest*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 848, *Reference Rate Reform*

ASC 852, *Reorganizations*

ASC 855, *Subsequent Events*

ASC 860, *Transfers and Servicing*

ASC 905, *Agriculture*

ASC 915, *Development Stage Entities*

ASC 930, *Extractive Activities — Mining*

ASC 944, *Financial Services — Insurance*

ASC 946, *Financial Services — Investment Companies*

ASC 954, *Health Care Entities*

ASC 958, *Not-for-Profit Entities*

ASC 960, *Plan Accounting — Defined Benefit Pension Plans*

ASC 970, *Real Estate — General*

ASC 985, *Software*

ASUs

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

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 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

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 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

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

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

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

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

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* — a consensus of the FASB Emerging Issues Task Force

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

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

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-20, *Technical Corrections and Improvements to Topic 606,* Revenue From Contracts With Customers

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

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

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

ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

ASU 2018-10, *Codification Improvements to Topic 842,* Leases

ASU 2018-11, *Leases (Topic 842): Targeted Improvements*

ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

ASU 2019-01, *Leases (Topic 842): Codification Improvements*

ASU 2019-04, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses*, Topic 815,* Derivatives and Hedging*, and Topic 825,* Financial Instruments

ASU 2019-05, *Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*

ASU 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

ASU 2019-11, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses

ASU 2020-01, *Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815* — a consensus of the FASB Emerging Issues Task Force

ASU 2020-02, *Financial Instruments — Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02*, Leases (Topic 842)

ASU 2020-03, *Codification Improvements to Financial Instruments*

ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*

ASU 2020-05, *Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*

ASU 2020-06, *Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*

ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*

ASU 2021-04, *Earnings per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — a consensus of the FASB Emerging Issues Task Force

ASU 2021-05, *Leases (Topic 842): Lessors — Certain Leases With Variable Lease Payments*

ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities From Contracts With Customers*

ASU 2021-09, *Leases (Topic 842): Discount Rate for Lessees That Are Not Public Business Entities*

ASU 2022-01, *Derivatives and Hedging (Topic 815): Fair Value Hedging — Portfolio Layer Method*

ASU 2022-02, *Financial Instruments — Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures*

ASU 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*

ASU 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*

ASU 2023-01, *Leases (Topic 842): Common Control Arrangements*

ASU 2023-05, *Business Combinations — Joint Venture Formations (Subtopic 805-60): Recognition and Initial Measurement*

ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*

ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*

ASU 2024-02, *Codification Improvements — Amendments to Remove References to the Concepts Statements*

ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*

ASU 2025-01, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*

Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 8, *Conceptual Framework for Financial Reporting — Chapter 4*, Elements of Financial Statements

Invitations to Comment

No. 2021-004, *Agenda Consultation*

No. 2025-ITC100, *Agenda Consultation*

Proposed ASUs

No. 2017-280, *Consolidation (Topic 812): Reorganization*

No. 2019-790, *Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting*

No. 2019-800, *Codification Improvements*

No. 2024-ED100, *Derivatives and Hedging (Topic 815) and Revenue From Contracts With Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for a Share-Based Payment From a Customer in a Revenue Contract*

No. 2024-ED200, *Derivatives and Hedging (Topic 815): Hedge Accounting Improvements*

No. 2024-ED400, *Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*

No. 2024-ED700, *Government Grants (Topic 832): Accounting for Government Grants by Business Entities*

No. 2024-ED910, *Environmental Credits and Environmental Credit Obligations (Topic 818)*

Other

FASB Staff *Revenue Recognition Implementation Q&As*

IFRS Literature

IFRS 2, *Share-Based Payment*

IFRS 3, *Business Combinations*

IFRS 9, *Financial Instruments*

IFRS 10, *Consolidated Financial Statements*

IFRS 11, *Joint Arrangements*

IFRS 12, *Disclosure of Interests in Other Entities*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 1, *Presentation of Financial Statements*

IAS 7, *Statement of Cash Flows*

IAS 10, *Events After the Reporting Period*

IAS 12, *Income Taxes*

IAS 17, *Leases*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IAS 21, *The Effects of Changes in Foreign Exchange Rates*

IAS 27, *Separate Financial Statements*

IAS 32, *Financial Instruments: Presentation*

IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*

IAS 38, *Intangible Assets*

IAS 40, *Investment Property*

Lease Liability in a Sale and Leaseback: Amendments to IFRS 16

IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 162(a), "Trade or Business Expenses; General"

Section 163(j), "Interest; Limitation on Business Interest"

Section 174, "Amortization of Research and Experimental Expenditures"

Section 197, "Amortization of Goodwill and Certain Other Intangibles"

Section 382, "Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change"

Section 409A, "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

PCAOB Literature

Auditing Standard 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion*

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

SEC Literature

Final Rule Releases

No. 33-10786, *Amendments to Financial Disclosures About Acquired and Disposed Businesses*

No. 33-11126, *Listing Standards for Recovery of Erroneously Awarded Compensation*

No. 33-11265, *Special Purpose Acquisition Companies, Shell Companies, and Projections*

No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors* [stayed]

No. 34-95607, *Pay Versus Performance*

FRM

Topic 1, “Registrant’s Financial Statements”

Topic 2, “Other Financial Statements Required”

Topic 3, “Pro Forma Financial Information”

Topic 5, “Smaller Reporting Companies”

Topic 7, “Related Party Matters”

Topic 10, “Emerging Growth Companies”

Topic 12, “Reverse Acquisitions and Reverse Recapitalizations”

Interpretive Releases

No. 33-9106, *Commission Guidance Regarding Disclosure Related to Climate Change*

No. 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*

Regulation S-K

Item 10(e), “General: Use of Non-GAAP Financial Measures in Commission Filings”

Item 101, “Description of Business”

Item 103, “Legal Proceedings”

Item 201, ”Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters”

Item 302, “Supplementary Financial Information”

Item 303, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”

Item 305, “Quantitative and Qualitative Disclosures About Market Risk”

Item 308, “Internal Control Over Financial Reporting”

Item 402, “Executive Compensation”

Item 404, “Transactions With Related Persons, Promoters and Certain Control Persons”

Item 407, “Corporate Governance”

Item 503, “Prospectus Summary”

Regulation S-X

Rule 1-02(w), “Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary”

Article 2, “Qualifications and Reports of Accountants”

Rule 3-01, “Consolidated Balance Sheet”

Rule 3-02, “Consolidated Statements of Comprehensive Income and Cash Flows”

Rule 3-03, “Instructions to Statement of Comprehensive Income Requirements”

Rule 3-04, “Changes in Stockholders’ Equity and Noncontrolling Interests”

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 3-10, “Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered”

Rule 3-12, “Age of Financial Statements at Effective Date of Registration Statement or at Mailing Date of Proxy Statement”

Rule 3-13, “Filing of Other Financial Statements in Certain Cases”

Rule 3-14, “Special Instructions for Financial Statements of Real Estate Operations Acquired or to Be Acquired”

Rule 3-16, “Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered”

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(n), “General Notes to Financial Statements; Accounting Policies for Certain Derivative Instruments”

Rule 5-02, “Commercial and Industrial Companies; Balance Sheets”

Rule 5-03, “Commercial and Industrial Companies; Statements of Comprehensive Income”

Article 8, “Financial Statements of Smaller Reporting Companies”

Rule 10-01(b), “Interim Financial Statements; Other Instructions as to Content”

Article 11, “Pro Forma Financial Information”

Rule 11-01 “Presentation Requirements”

Rule 11-02(a), “Preparation Requirements; Form and Content”

Article 15, “Acquisitions of Businesses by a Shell Company (Other Than a Business Combination Related Shell Company)”

SAB Topics

No. 1.B.3, “Financial Statements; Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity: Other Matters”

No. 1.M, “Financial Statements; Materiality”

No. 5.A, “Miscellaneous Accounting; Expenses of Offering”

No. 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

No. 14, “Share-Based Payment”

- No. 14.B, “Transition From Nonpublic to Public Entity Status”
- No. 14.D, “Certain Assumptions Used in Valuation Methods”
    - No. 14.D.1, “Expected Volatility”
    - No. 14.D.2, “Expected Term”

Securities Act of 1933

Rule 144, "Persons Deemed Not to Be Engaged in a Distribution and Therefore Not Underwriters — General Guidance"

Rule 405, "Definitions of Terms"

Section 6(e), "Commissions, Allowances, Discounts, and Other Fees"

Securities Exchange Act of 1934

Rule 17a-5, "Reports to Be Made by Certain Brokers and Dealers"

Section 3(a)(80), "Definitions and Application of Title; Emerging Growth Company"

Section 13(a), "Periodical and Other Reports"

Section 15(d), "Supplementary and Periodic Information"

TRG Agenda Papers

TRG Agenda Paper 6, *Customer Options for Additional Goods and Services and Nonrefundable Upfront Fees*

TRG Agenda Paper 11, *October 2014 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 41, *Measuring Progress When Multiple Goods or Services Are Included in a Single Performance Obligation*

TRG Agenda Paper 44, *July 2015 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 48, *Customer Options for Additional Goods and Services*

TRG Agenda Paper 54, *Considering Class of Customer When Evaluating Whether a Customer Option Gives Rise to a Material Right*

TRG Agenda Paper 55, *April 2016 Meeting — Summary of Issues Discussed and Next Steps*

Superseded Literature

AICPA Accounting Interpretation

AIN-APB 25, *Accounting for Stock Issued to Employees: Accounting Interpretations of APB Opinion No. 25*

AICPA Accounting Statement of Position

96-1, *Environmental Remediation Liabilities*

EITF Abstracts

Issue No. 00-21, "Revenue Arrangements With Multiple Deliverables"

Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)"

Issue No. 01-10, "Accounting for the Impact of the Terrorist Attacks of September 11, 2001"

Issue No. 03-17, "Subsequent Accounting for Executory Contracts That Have Been Recognized on an Entity's Balance Sheet"

Issue No. 08-6, "Equity Method Investment Accounting Considerations"

Issue No. 09-2, "Research and Development Assets Acquired in an Asset Acquisition"

Issue No. 09-4, "Seller Accounting for Contingent Consideration"

FASB Concepts Statement

No. 6, *Elements of Financial Statements* — a replacement of FASB Concepts Statement No. 3 (incorporating an amendment of FASB Concepts Statement No. 2)

FASB Interpretation

No. 14, *Reasonable Estimation of the Amount of a Loss* — an interpretation of FASB Statement No. 5

FASB Statements

No. 5, *Accounting for Contingencies*

No. 52, *Foreign Currency Translation*

No. 95, *Statement of Cash Flows*

No. 114, *Accounting by Creditors for Impairment of a Loan* — an amendment of FASB Statements No. 5 and 15

No. 123(R), *Share-Based Payment*

No. 133, *Accounting for Derivative Instruments and Hedging Activities*

No. 141, *Business Combinations*

No. 141(R), *Business Combinations*

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

Other

California Climate Legislation

AB-1305, *Voluntary Carbon Market Disclosures*

SB-219, *Greenhouse Gases: Climate Corporate Accountability: Climate-Related Financial Risk*

SB-253, *Climate Corporate Data Accountability Act*

SB-261, *Greenhouse Gases: Climate-Related Financial Risk*

European Sustainability Reporting Standards (ESRS)

Regulation (EU) 2023/2772 of 31 July 2023 Supplementing Directive 2013/34/EU of the European Parliament and of the Council as Regards Sustainability Reporting Standards

- ESRS 1, *General Requirements*
- ESRS 2, *General Disclosures*

E.U. Corporate Sustainability Reporting Directive (CSRD)

Directive 2022/2464/EU of the European Parliament and of the Council of 14 December 2022 Amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as Regards Corporate Sustainability Reporting

EU Taxonomy Regulation

Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the Establishment of a Framework to Facilitate Sustainable Investment, and Amending Regulation (EU) 2019/2088

IFRS Sustainability Disclosure Standards

IFRS S1, *General Requirements for Disclosure of Sustainability-Related Financial Information*

IFRS S2, *Climate-Related Disclosures*

Non-Financial Reporting Directive (NFRD)

Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 Amending Directive 2013/34/EU as Regards Disclosure of Non-Financial and Diversity Information by Certain Large Undertakings and Groups

Proposed European Commission Literature

Omnibus I — COM(2025) 80, Proposal for a Directive of the European Parliament and of the Council Amending Directives (EU) 2022/2464 and (EU) 2024/1760 as Regards the Dates From Which Member States Are to Apply Certain Corporate Sustainability Reporting and Due Diligence Requirements

Omnibus I — COM(2025) 81, Proposal for a Directive of the European Parliament and of the Council Amending Directives 2006/43/EC, 2013/34/EU, (EU) 2022/2464 and (EU) 2024/1760 as Regards Certain Corporate Sustainability Reporting and Due Diligence Requirements

Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AFSI	adjusted financial statement income
AI	artificial intelligence
AICPA	American Institute of Certified Public Accountants
AIN	AICPA Accounting Interpretation of an APB Opinion
AMT	alternative minimum tax
ANDA	abbreviated new drug application
APB	Accounting Principles Board
API	active pharmaceutical ingredient
ARO	asset retirement obligation
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
AUD	Australian dollar(s)
BC	Basis for Conclusions
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
C&DI	Compliance and Disclosure Interpretation
CAM	critical audit matter
CAQ	Center for Audit Quality
CARB	California Air Resources Board
CARES Act	Coronavirus Aid, Relief, and Economic Security Act

Abbreviation	Description
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
CMO	contract manufacturing organization
CODM	chief operating decision maker
CPU	central processing unit
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
EC	European Commission
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EFRAG	European Financial Reporting Advisory Group
EGC	emerging growth company
EITF	Emerging Issues Task Force
ELOC	equity line of credit
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
ESRS	European Sustainability Reporting Standards

Abbreviation	Description
E.U.	European Union
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FPI	foreign private issuer
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVO	fair value option
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GDP	gross domestic product
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GloBE	Global anti-Base Erosion
GPO	group purchasing organization
GPU	graphics processing unit
HAFWP	how and for what purpose
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
ICFR	internal control over financial reporting
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research

Abbreviation	Description
IOSCO	International Organization of Securities Commissions
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
ISSB	International Sustainability Standards Board
IT	information technology
ITC	invitation to comment
JOBS Act	Jumpstart Our Business Startups Act
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
LLM	large language model
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MNE	multinational enterprise
MSL	medical science liaison
NDA	new drug application
NFP	not-for-profit (entity)
NFRD	Non-Financial Reporting Directive
NIH	National Institutes of Health
NLP	natural language processing
NOL	net operating loss
NOPA	notice of proposed adjustment
NQSO or **NSO**	nonqualified stock option
OCA	SEC Office of the Chief Accountant
OCI	other comprehensive income

Abbreviation	Description
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PIPE	private investment in public equity
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimental
RAM	random-access memory
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right-of-use
SaaS	software as a service
SAB	SEC Staff Accounting Bulletin
SAFE	simple agreement for future equity
SEC	U.S. Securities and Exchange Commission

Abbreviation	Description
Securities Act	Securities Act of 1933
SEPA	standby equity purchase agreement
SG&A	selling, general, and administrative
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting company
S&P 500	Standard & Poor's 500 Index
TCFD	Task Force on Climate-related Financial Disclosures
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TSA	transition services agreement
USD	U.S. dollar(s)
UTB	unrecognized tax benefit
VCO	voluntary carbon offset
VIE	variable interest entity
VWAP	volume-weighted average daily market price
XBRL	eXtensible Business Reporting Language