# Integrated Knowledge Management (IKM) Volume 9

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### Integrated Knowledge Management (IKM) Volume 9

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### 1. Open-Source

#### 1.1. How to Contribute

For community members and users who would like to collaborate and contribute, please visit the 'Community' tab on the <u>IMK.dev</u> website or go directly by typing *ikm.dev/community*.

#### 1.2. What is Open-Source?

Open-source software makes its source code, blueprints, documentation, and other products publicly available for users to modify, contribute to, and distribute. Open-source software uses a decentralized approach to software development that supports open collaboration, testing, and improvements from the community of users. In open-source, no one group is solely responsible for maintaining or improving software because peer-to-peer production of code and documentation is encouraged. While a governing body may exist in practice to maintain the software and ensure contributions meet community guidelines, they may not hold special rights to the software. Reasonable guidelines, such as extensive documentation procedures, enhance the benefits and trust in open-source solutions, while simultaneously preventing an "anything goes" mentality.

### 1.3. Why Does Open-Source Matter?

The current restrictive and proprietary nature of software licensing within the healthcare ecosystem significantly hinders interoperability, particularly by preventing or restricting community engagement and contributions that could improve the software or code to meet emerging needs. To achieve lossless data exchanges between and within systems, the Health Information Technology (IT) community must consider open-source software and open-source licensing models. While these licenses enable use, regardless of intent, and the ability to modify, adapt, and extend software with minimal restrictions, they also establish rules of the road and codify best practices to ensure adoptability and ease of use for both the initial user and the broader downstream community. Open-source licensing will support the public-private consortium needed to address gaps created by varying rates of adoption and implementation of proprietary software.

Due to the decentralization and wide-spread availability of open-source software, errors and bugs are found much quicker because the code is utilized in a variety of contexts and stretched much farther. Instead of a single development team being tasked with identifying and repairing errors, users can serve as developers and contribute to addressing errors much faster. As a result, open-source software employs a high degree of modularity where it can be adaptive and flexible to the diverse needs of its users.

Allowing for open licensing encourages improvements to terminology and standards by ancillary bodies. The open licensing also creates a more robust and flexible system that can adapt to the varying needs of organizations.

### 1.4. Preference for Open-Source

Open-source software is preferred and is managed through open-source licensing. A permissive license will provide source code to users, carries minimal restriction over adaption, modification, and distribution of intellectual property of organizations, and allows the issuing body to impose some restrictions, such as monetization. However, the permissive license does not exert special rights to derivative works. Permissive licensing throughout the foundational architecture, terminology knowledge, and statement model layers removes barriers imposed on modifications and extensions and improves the compatibility of different terminologies to support a common understanding of knowledge.

# 2.1. The Current State of Healthcare Knowledge Management

Over the last decade, billion dollars have been poured into achieving interoperability in the healthcare industry. Patients, providers, and healthcare agencies have collectively identified the need for a more harmonized, integrated health system to solve the challenges surrounding clinical data, such as its interpretability and accuracy. The current structure of the healthcare ecosystem continues to fail in providing adequate structures conducive to collaborative, community-based solutioning. A review in 2021 of American Hospital Association Information Technology survey data found that by 2018, 98.3% of hospitals have adopted Electronic Health Record (EHR) systems – the primary creators and curators of digital health data. Yet, across the board, health systems have struggled to move beyond simple adoption and implement advanced use in patient engagement and clinical data analytics. [1] Notably, critical access hospitals in rural areas were less likely to demonstrate advanced usage with an expanding deficit to their counterparts in clinical data analytics since 2015, leading to gaps in patient access of quality healthcare.

Today, many hospital systems have the goal of improving data interoperability within and beyond their system. To be truly useful, clinical data must move through numerous systems without loss of meaning. In an idealized situation, data transfers would complete a single round-trip with total integrity intact. In reality, only 22% - 68% of data integrity is successfully preserved through its transfer journey. [2] A patient's record may correctly showcase the correct numerical result from a test but could lose the context and meaning surrounding the test. Ever-increasing system complexity and resulting low-quality data, however, has ultimately impacted the quality of care across the healthcare ecosystem, such as inefficiencies of redundant testing and procedures being ordered, expanding the timeframe of care for patients. Additionally, the very systems that have been designed to integrate EHRs into the health space can create barriers to interoperability through closed, proprietary systems. Multiple, sometimes competing, encoding standards have been developed over the last few decades to address the varying formats clinical data embodies. Some clinical standardization forms, however, are very broad in its acceptance criteria resulting in large amounts of variation between encodement while others are too restrictive, limiting the situations in which they can be utilized. As a result, the need for a consistent form to map standards to and between other standards in creation of a common model is required for improvement of interoperability within the healthcare landscape where clinical decisions can be captured regardless of what point they originate in patient care.

#### **Defining a Key Issue: Restrictive Healthcare Licenses**

The root cause of insufficiencies within health IT is not limited solely to a group of vendors or organizations but is rather a foundational issue that permeates throughout the ecosystem. Restrictive licenses are just one of these causes and are used in varying forms across the landscape. However, this spurs unintended consequences of limiting harmonization. Instead of just treating the symptomatic results of poor data quality, attention should also be spent understanding the reasons beneath recurring pain points. Various standards have been developed to compete and improve upon the limitations of other encoding standards. As multiple organizations, such as by clinicians, laboratorians, and providers integrate patient data together, the need of various standards to transfer openly and completely becomes even more apparent. A piecemeal approach has occurred where different standards carry licensing restrictions to protect against mod-

ifications and extensions of their code for proprietary oversight, creating confusion on how and to what extent standards can be shared. Healthcare data standard organizations seek to protect their software and standards, by design, from unauthorized subversion, modification, and duplication of their work through their licensing agreements. These restrictions often allow for direct oversight of derivative works from the issuing body as well as monetization from commercial usage of their product. In a highly profitable landscape, restrictive licenses allow organizations to prevent their work from being duplicated by rivals and seek longevity in the marketplace. Proprietary licensing leads to siloed operations by providers and developers, as well as higher implementation costs, limiting stronger adoption. These restrictive licenses can pose challenges on the ease of transfers within and between systems and are creators of insufficiencies within health IT. For example, issuing standards do not always fit into the exact context practitioners need and require adaption into localized knowledge. Licenses often prevent against local knowledge being shared between system and require a mapping to an existing code for meaningful data usage. Data integrity can be impacted as there may be no exact match that encompasses all the information from local codes and be transferred incompletely. Tools to aid in standardization may be restricted due to modification and extension restrictions within proprietary licenses.

The current restrictive and proprietary nature of licensing within the healthcare ecosystem significantly hinders interoperability. To achieve lossless data exchanges between systems, the Health IT community must consider movement towards open-source software and open-source licensing models. Gaps created by varying rates of adoption and implementation requires various avenues of collaboration within the Integrated Knowledge Management (IKM) community to address these issues within the entire Health IT ecosystem.

### 2.2. The Case for a More Open Future in Healthcare

The rapid expansion of technology and connectivity has created ill-defined guidelines on management and ownership of data. As a result, researchers and users find themselves navigating different and competing guidance on utilizing and adapting software for their own needs. One of the main movements on expanding access and resolving conflict between proprietary systems is that of granting wide, sweeping rights through the open-source movement. Notably, open-source software like Mozilla Firefox has enabled web access utilized by millions every year. Additionally, open software systems, like Apache 2.0, have had broad adoptive use because it allows software to be used for any purpose, modified or otherwise.

The following sections aim to define the open-source software and licensing more clearly:

#### **Open-Source Software (OSS)**

There are two branches of software utilized by individuals and companies: open-source software and proprietary, or closed-source, software. At the most theoretical level, in an open-source environment, the source code is freely available and accessible to its end-users regardless of their intent, be it for personal or commercial use. The term "free" is under debate regarding the cost of accessing the software and under contention on if the source code can be monetized for access. Here, free is used as in libre, or freedom, and not necessarily in cost. The discussion of free licensing extends to freedoms guaranteed through the licensing for the software, and not in the context of the monetary cost to access the software. Many software systems are considered to be open-source but are not free from implementation cost. There are third-party costs associated with integrating and maintaining open-source.

The Free Software Foundation (FSF) defines free as in:

• The freedom to run the program as you wish, for any purpose (freedom 0).

- The freedom to study how the program works and alter it so it computes as you wish (freedom 1). Access to the source code is a precondition for this.
- The freedom to redistribute copies so you can help others (freedom 2).
- The freedom to distribute copies of your modified versions to others (freedom 3). [3]

This is controlled in the forms of licenses and is discussed further below. Closed source systems protect the source code and modifications cannot be made where the end-user can only execute the code within the confines of the original intent of the creator.

In open-source, no one group is solely responsible for the software because it allows for a peer-to-peer production of codes and documentation. A governing body may exist to oversee and maintain the software as long as no one group holds special rights to the software. Due to the decentralization of software, errors and bugs are found much quicker because the code is utilized in a variety of contexts and stretched much farther. Instead of a single development team being tasked with identifying and repairing errors as they are found, users can also be developers and contribute to identifying errors much faster. As a result, open-source software utilizes a high degree of modularity where it can be adaptive and flexible to the diverse needs of its users.

In its purest form, open-source software lowers the burden of buy-in required by consumers where they can build on the work of others through a collaborative community without reinvention. Lower implementation cost and maintainenance of open-source software helps expand the possible consumer base. It is not restricted to those who can devote the time and resources to stand up the required infrastructure and knowledge base. Instead, end-users can guide and shape the software to their niche rather than be limited to the specific intended usage at its inception. The creation of open-source leads to a symbiotic ecosystem where software is more robust and applicable than its closed counterparts.

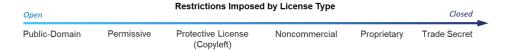
Many software systems today utilize qualities of open-source software but lie in a gray area where they maintain proprietary techniques. These limits are imposed by their licensing models through their enduser agreements.

#### Open-Source Licensing (OSL)

The implementation of open-source software is managed in-hand through open-source licensing (OSL). The license of the software sets out the guidelines on the usage and implementation of the specific version of software being used. The license acts as a copyright agreement where organizations and creators can control the distribution, duplication, and modification of their work.

There are many different types of licenses, as seen in Figure 2.1 below, and are often created to be intentionally vague to apply to a multitude of situations and preserve the rights of the licensor:

Figure 2.1. Restrictions Imposed by License Type



**Public-Domain**: Public domain refers to any information, software, or intellectual property that carries no restrictions in regard to copyright law. It is free to use by any individual. No one group can exercise control over it. In a software setting, source code must be provided.

**Permissive License**: Also known as an open-source license. This type of license carries minimal restriction over adaption, modification, and distribution of intellectual property of organizations. An issuing body

may impose some restrictions, such as the monetization, but it does not exert special rights to derivative works. In a software setting, source code must be provided.

**Protective License:** This type of license, also called a copyleft license, grants rights on modification and redistribution but also requires derivative works to include and grants the same rights of the original license. Similar to public domain and permissive licenses, source code must also be accessible.

**Noncommercial**: The license only grants special rights to be used in a noncommercial setting where an external entity may exercise proprietary control or monetization of the applicable intellectual property. This can also decrease the cost of access, especially for organizations for academic or research purposes.

**Proprietary**: The most traditional form of licensing where no rights must be granted to other entities. There are varying significant restrictions on modification and distribution, where it is often disallowed completely.

**Trade Secret**: Often left unpublished, information is not open to the public or non-entity members in any form. It is the most restrictive, private type of licensing. In software, no source code is available.

Open-source licensing is seen as a method to resolve the dispute between unauthorized copying and distribution of content as well as the copyright laws that have been created to protect individual and businesses of their own work. [4] Instead of users finding ways to circumvent barriers of access to content, the license serves as a pathway on how to freely access and modify software to the needs of users while protecting the proprietary interests of the originator. In this context, discussion surrounding the term of "free" applies here as well as in open-source software. Many software systems are considered to be open-source and utilize an open-source license but are not free in cost to the licensee.

Open-source licensing agreements give access to software that may have been prevented under copyright law. These types of licenses enable use regardless of intent and the ability to modify, adapt, and extend software with minimal restrictions. The license establishes rules of the road and codifies best practices to enable adoptability and ease of use for both the initial user and the broader downstream community. For example, many licenses require modifications to be disclosed and thoroughly documented for third-party individuals to avoid endorsements and confusion regarding what has been published directly from organizations themselves.

In practice, many licenses are not considered open-source due to certain conditions like distribution, access, and modification being prohibited. It is important to note that the quality of software and source code is not inherently affected by the structure of the license. A balance, however, is required ensuring that the licenses do not cause unintended consequences surrounding the proper development and evolution of the code by the user. [5]

### 2.3. Examining License Agreements in Action

For many organizations, it is unrealistic to fully adopt all parts of open-source software and licensing. Organization's structure licenses dependent on the intended usage of software and codes and aim to embody qualities of open-source. For example, an individual may be able to access software and source code for no-cost or at a greatly reduced cost if it is meant for an academic usage. The moment where the user would like to adapt, transmute, and distribute software, they will often need a different license such as a commercial one. Rather than being purely open or closed source, in application, many organizations lie somewhere in the middle where commercialization of parts of their software support the ongoing research, development, and maintenance of itself. Organizations argue that the monetization of their software also allows them to create detailed guidance for implementation as well as more direct support to its customers while also protecting the proprietary source and implementation of its product. This can contribute to unintended downstream effects that require a multistep approach to solving. Advocacy towards open-source, permissive licenses is one aspect to solutioning.

Users are often left to determine their obligations to different licenses, especially when wanting to combine related software. How do researchers, laboratorians, and health providers navigate the intentional vague complexity of licenses when attempting to solve interoperability? Instead, they experience restrictions and lock-in from standards that act as a hinderance to solving patient problems. Two related but distinguishable implication of licenses are [6]:

- 1. The explicit terms and rights maintained on content derived from software, and
- 2. The incompatibility of licensing in competing and related standards.

The current siloed approach of licensing models prevents interoperability within health IT and results in lower quality data with unattended, downstream patient effects.

Case-Study: LOINC® and SNOMED International Licensing Agreements

Logical Observation Identifiers Names and Code® (LOINC®) and Systemized Nomenclature of Medicine – Clinical Terms® (SNOMED CT®) are two of the most widely used health data standards in the U.S. for clinical terminology. LOINC® is overseen by the Regenstrief Institute and utilizes a global team for maintaining, developing, and updating guidance on its terminology with the vision of promoting open terminology standards across every clinical information system [7]. LOINC® advocates for open terminology standards but does not issue an open-source license. Instead, all users are required to hold a license to utilize LOINC®, with some licenses requiring a fee to implement and utilize the full functionality of LOINC®. Similarly, SNOMED-CT® is overseen by SNOMED International with the intent to support, maintain, and implement SNOMED CT®. All users are required to accept SNOMED International's licensing agreement through an end-user agreement and are issued a proprietary license with some requiring a fee depending on the usage and intent of the license. Both organizations issue guidance on new and existing codes to reflect current events and needs at least biannually by engaging in a rigorous feedback function where users can engage. SNOMED International is moving towards more timely standard updates, not limited to the biannual timeline, especially for rapid developing arenas, such as COVID-19.

#### Where Licenses Break Interoperability: Redistribution and Modification

The Regenstrief institute highlights guiding principles such as openness and agility in improving and widening LOINC®'s implementation. Regenstrief does not allow the distribution of modified codes under their license. Often, health systems will adapt an existing code to better represent their localized environment where there is no one-for-one match. Users must create their own solution limited to the licensing agreement, engage in a feedback process with the Regenstrief Institute, and wait until a new code is issued directly from Regenstrief to be able to share between systems.

SNOMED International does not allow for derivative work or extensions to be created if it has not already been issued a Namespace Identifier. Modifications are disallowed under their SNOMED CT® Affiliate license and must go through a feedback process where users can petition for added codes in a future release cycle. This is to avoid confusion and ambiguity of SNOMED International codes and prevent against inconsistencies between systems. [8] As a result there will be many forms of similarly derived codes in a localized format.

This waiting cycle creates gaps that directly impact the quality and interoperability of data. While organizations petition to have new codes created, they must continue to standardize their codes before their data is transferred to another system. During this step, data can be lost during the transfer from a local code to a standard LOINC® or SNOMED® code. Doctors may lose the much-needed context surrounding patient care, leading to redundancy in additional ordered tests and referrals. Moreover, the issuance of new codes does not circumvent the usage of localized knowledge. New codes can be used in place of local knowledge, but it can also be further adapted into knowledge for the specific needs of practitioners. This does not solve the transfer errors that can occur when local codes are standardized.

## 2.4. Putting a More Open Healthcare Ecosystem Into Practice

The Integrated Knowledge Management (IKM) community has been longing to address proper standardization encodement of healthcare information across ever changing system. Many avenues of collaboration would help solve the data quality and interoperability issue that the healthcare IT ecosystem is facing. The meaningful semantic difference within terminologies requires preservation to prevent against varying clinical interpretations and treatment. An **IKM approach** can act as a method to standardize clinical statements and terminologies by providing abstraction and elimination of unnecessary complexity. Instead of a local code being incorrectly mapped to a standard code, the IKM platform would provide guidance on the most applicable codes and reduce data loss by ensuring a consistent, reproducible format allowing for the same test to be represented the same way, every time. Proper achievement requires collaboration across government regulatory bodies, public health laboratories, private healthcare systems, and In-Vitro-Diagnostic (IVD) device manufacturers. This also extends to the bodies that oversee terminology standards and the licensing agreements governing them.

For successful implementation of an integrated knowledge ecosystem, licensing bodies should implement components of open-source licensing, specifically on modification and distribution of copyrighted standards. Currently, the process that exists on how licenses work together in common spaces and the subsequent requirements are ambiguous. Would the implementation of a third-party software trigger licensing restrictions and inhibit the willingness of organizations to adopt them? Is the usage of an IKM platform by an organization to reconcile local codes considered to be an extension of a modified code, disallowed under the existing licensing structure? Some licenses consider any work to be referential to be a "derivative" without fully specifying the scope of the reference. This is seen, for example, in the form of the GNU's Not Unix (GNU) General Public License (GPL) and in references to GPL licensed libraries. [9] The navigation of differing licenses and determining the varying responsibilities imposed by them can be a costly, time-consuming burden that often acts as a barrier for meaningful progress. It can quickly become a convoluted process that inhibits success of implementation, unintended by the licensor and their vision of interoperability as seen in LOINC®. Licenses must walk a tightline on preventing extension of standards, thereby slowing down the evolution of these standards, and allowing full extensions that can subvert the standard in and of itself, creating confusion where modifications look to be endorsements by the issuing body. [5]

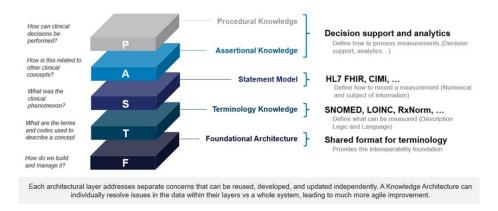
In practice, strong open-source licenses can encourage the development and evolution of standards without subversion of standards through guardrails on community contributions. Instead of a few chosen contributors, solutions can be developed openly with the collaboration of multiple stakeholders where solutioning becomes more robust and agile to the various needs of its users. Reasonable guidelines, such as extensive documentation procedures especially in extensions, enhances the trust within open-source solutions and allow for the benefits of open-source without allowing an "anything goes" mentality where confusion ensues. Additionally, open-source licenses can continue to protect against impersonations and false endorsements through their agreements.

#### Open-Source Licensing Within a Knowledge Architecture

A Knowledge Architecture is a framework for clinical information that is organized into distinct layers such that each higher layer relies upon artifacts from the lower layer. It aims to define a standardized form of clinical statements and harmonize existing terminologies together into a single system.

A knowledge architecture intended for use in the current health IT ecosystem is listed below:

Figure 2.2. Layers Within Knowledge Architecture



Rather than a broad transformation of existing licenses in a purely open-source model, not all components of software and standard licensing require a pivot away from proprietary oversight to lead to successful implementation of an IKM ecosystem. The commercial usage of aspects of licenses allows for ongoing support and maintenance of software and standards. The move towards a permissive license does not require a seismic shift in organization structure or its ability monetize its commercial license, especially for organizations already promoting open-standards. Allowing for open-licensing encourages improvements of terminology and standards by ancillary bodies and creates a more robust, flexible system that can further adapt into the varying needs of organizations.

Data harmonization improves when foundational layers of Knowledge Architecture are integrated into common, collective sources of data. If utilized correctly under a Knowledge Architecture, a single-data journey can be completed with integrity intact every time. Permissive licensing throughout the foundational architecture, terminology knowledge, and statement model layers removes barriers imposed on modifications and extensions and instead aids in the creation of common understandings of knowledge. The Terminology Knowledge layer within Knowledge Architecture oversees the structure of medical terminologies, such as the language and semantic hierarchy within data. It is in this layer where the IKM platform arbitrates the valid codes and expressions to be used in higher layers. Currently, the usage of terminology standards like SNOMED CT®, LOINC®, and additional standards pose questions regarding compatibility due to modification and extensions limitations. The complexity widens when further standards based on other standards are integrated further in the terminology layer, like the Laboratory Interoperability Data Repository (LIDR) and the TermINology Knowledge Architecture (Tinkar). The loss of data often occurs in this layer and breaks the functionality of standards where local codes are mapped to the incorrect standard codes. The IKM platform aims to solve this issue by harmonizing standards but cannot be successfully implemented unless the underlying licenses allow an IKM platform to reconcile variances. In the Statement Model, the artifacts as defined below are reused and demonstrate how the data elements should be packaged into clinical statements through clinical formatting, such as Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) or Clinical Informational Modeling Initiative (CIMI). The shift towards a permissive license in regard to terminologies and standards improves the compatibility of how different terminologies work together and thereby is integral to the functionality of higher layers and interoperability overall.

#### 2.5. Conclusion

Achievement of interoperability within healthcare systems requires a multi-faceted approach through the extensive collaboration of various stakeholders involved. In its current form many licenses serve as unintended barriers to interoperability where downstream patient harm can occur. The increasing interconnectedness of industries and partners requires a reevaluation of existing licensing structures that impose barriers often antithetical to goals set out by issuing organizations themselves. For solutions like an Inte-

grated Knowledge Platform to succeed, licensing must be structured to support and encourage growth of ancillary bodies. The adoption of open-source licensing encourages diversity of thought where stronger software often results to the benefit of organizations. Advocacy towards open-source licensing must also occur internally by managing teams. Together, common solutioning reduces siloed company operations, moving one step closer to harmonization across the health IT landscape.

### 2.6. Appendix

	LOINC®	SNOMED CT®
What is the type of license utilized?	licenses throughout. It is not considered to be open-source, especially under the commercial agreement.	SNOMED CT® is not considered open-source and instead issues proprietary licenses. SNOMED CT® has a variety of licenses dependent on the usage and intent, with some requiring a fee.
	Notably, all users are required to hold a license to utilize LOINC®.	SNOMED CT® requires all users to have a license.
Who owns and maintains the standard?	Regenstrief Institute oversees LOINC® and utilizes a global team to contribute to LOINC®. They oversee and are responsible for the maintenance of LOINC®, as well as issuing up-to-date guidance.	in part by the International Health Terminology Standards Development Organization (IHTSDO) to maintain and
What is the cost associated with usage?	use and is specified by its intent of the license holder. Nonprofit, academic, and individual licenses are available under a free license; however, a commercial license requires a fee to implement.	
What does redistribution look like?		SNOMED International redistribution is only allowed under a commercial license

	original license is included	as part of their license and
	in it. Limitations exist for	
	modified codes and cannot be	-
	redistributed without the consent	-
	of LOINC® copyright holders. If	
	the distribution is intended for	
	commercial usage, a commercial	Redistribution cannot be done
	license may be required with	in non-commercial licenses.
	associated fees.	Modifications of SNOMED
		International codes are allowed
		under certain distribution licenses
		but must maintain compatibility
		with the original SNOMED CT®
		as well as be clearly documented
		and labeled.
How often do releases occur?	Releases occur twice a year,	Releases occur in January and
Who contributes to what is	typically every 6 months.	July every year and contain
updated?	LOINC® utilizes a feedback	
		to reflect current events, similar to
	new codes as well as gathering	
	feedback from stakeholders,	
	regardless of license status. They	
	additionally test these codes and	
	1	
	update guidance on existing codes	
	to reflect current events (ex.	
	COVID-19).	

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### 3. Ecosystem

### 3.1. Notice

The Ecosystem chapter currently serves as a placeholder. In the near future, our team will develop, identify, and refine a content to be incorporated.