Guideline for
KAKUTEI of image information
v. 2.1

Public Interest Incorporated Association
Japanese Society of Radiological
Technology
August 18, 2014

Preface for English version

Japanese Society of Radiological Technology recognizes that more research papers to introduce or investigate Japanese practices should be also published in English.

Accordingly, the English version of “Guideline for KAKUTEI of image information” is created with the following intentions:

(a) initiatives driven by radiological technologists in Japan for improving care delivery are introduced to international societies with adequate context; and

(b) individuals who write research papers in English would be able to refer to this guideline as appropriate.

In the English version, the following two words are respectively kept in their original Japanese as they represent core theme of this guideline:

KAKUTEI is an act of storing image information for use as grounds for diagnosis in information systems such as PACS; and

KENZO is an operation of optimizing image quality before KAKUTEI.

While readers without experiences in Japanese practice may not be familiar with these operational concepts, we wish that they may become clearer throughout the text of this guideline.

For all readers of this English version, it is strongly advised that if in question, the original publication of the “Guideline for KAKUTEI of image information” in Japanese is referred to for clarification.

October 1, 2016
Public Interest Incorporated Association
Japanese Society of Radiological Technology

1. Introduction

The digitization of image information has not only improved the usability of medical images at medical institutions, leading to filmless environments, but has also enabled additional image processing, which aids diagnosis and the exchange of digital image information between medical institutions, including teleradiology.

Before the digitization of image information, it was difficult to modify images printed on film; thus, to ensure the traceability of image information, it sufficed to appropriately store physical films as grounds for diagnosis. However, with the proliferation of information systems, it has become common practice at medical institutions to create and store digitized image information whose content differs from that of conventional film-based image information. For example, it is not difficult to carry out additional image processing with the intention of increasing the value of its data or to overwrite an existing digital image entirely. In such cases, however, concerns about the provenance and authenticity of image information arise, since the original image may have been altered over time. In clinical practices in particular, it is obviously dangerous to alter the image information used by doctors as their grounds for diagnosis.

In order to deal with this problem and ensure the authenticity of necessary information, it is crucial to clarify the time at which image information became grounds for diagnosis and properly document where the responsibility for its creation and the obligation of its storage, reside. The Ministry of Health, Labor, and Welfare (MHLW) has published “Guideline for the Security Management of Medical Care Information Systems” (the MHLW security management guideline v. 4.3, March 2016) as a guideline for handling digitized medical information and the operation and management of medical information systems.

This guideline was prepared by the guideline creation group of the Japanese Society of Radiological Technology in FY 2009, declaring that “the KAKUTEI of image information is assumed as a duty of radiological technologists," as set forth in each medical institution’s policy and procedure manual and in accordance with the aforementioned security management guideline. Taking into consideration the operations particular to digital images, such as image processing and the procedure for handling image information at medical institutions, this guideline was specifically designed to guideline the KAKUTEI and storage of image information and to promote appropriate processes for the KAKUTEI and management of digital images.

This guideline is intended to demonstrate concepts that will aid medical institutions in determining how and when timing information is set for KAKUTEI and to clearly define it in their policy and procedure manual.

In the process preceding the KAKUTEI and storage of an image, there exist numerous operational procedures and policies unique to each medical institution, such as image quality optimization, the confirmation of supplemental information (also called KENZO), and physicians' methods for specifying information as grounds for diagnosis.

This guideline pays particular attention to the concept of the KAKUTEI of a record, which is necessary for the provision of authenticity, as required by the MHLW security management guideline, and requires clear definition in policy and procedure manuals with regard to the threshold and timing of the KAKUTEI of information of, for example, images obtained in exams.

Here, the "KAKUTEI of record" in imaging and "KENZO operations" in imaging are considered to be the outcome and the process of quality assurance, respectively. Because they are both important steps, this guideline treats them as reasonably sequential procedures. However, the introduction of a KENZO system designed for increased efficacy or operational convenience and the discussion of timing definitions for the KAKUTEI of a record are two dimensionally different concepts; hence, this guideline does not suggest that any specific KENZO system is required for the KAKUTEI of a record. Moreover, the definition of KENZO and appropriate image handling procedures, which are important responsibilities of medical personnel with clinical roles, are left for another discussion.

This guideline, recognizing the importance of KAKUTEI, establishes requirements for fulfilling the duties of a radiological technologist, with the expectation that any staff member can become responsible for the creation of image information (per an institution's policy and procedure manual). In addition, periodic review is planned to avoid the obsolescence of this guideline; please confirm that this is the latest version and be aware of future updates.

2. The scope of this guideline and intended image information of this guideline

This guideline is designed for persons involved in picture archiving and communication systems (PACS) or any other information systems dealing with image information, as well as those involved with those systems' operation, utilization, service and maintenance, or disposition.

Persons responsible for handling "radiographs," as indicated in Medical Care Law Enforcement Regulations Article 20, or "image information legally subject to storage," among other image information that requires protection of personal information, as in the "records of diagnoses" in Articles 21, 22, and 22.2 of the Medical Care Law (July 30 1948. Act No. 205), should be familiar with this guideline.

3. KAKUTEI and the creation responsibility of image information

This section clarifies the KAKUTEI and responsibility for the creation of image information as grounds for diagnosis and conditions regarding these responsibilities.

3.1. The provision of authenticity

The MHLW security management guideline states as a requirement for electronic storage, that "in order to electronically store documents required to be preserved by law, it is required that not only those digitized documents can be used without difficulty but also their accuracy is at sufficient level such as to being used as evidence of lawsuits."

Here, three criteria for the provision of authenticity, the provision of visual readability, and the provision of storage property are listed as legal conditions for electronically storing documents. Of these criteria, authenticity is a measure of whether the lawfully created document has been protected from false input, overwriting, erasure, or confusion and that the responsibility for its creation, as viewed by a third party, is clear.

3.2. KAKUTEI operations and creation responsibility

As institutional requirements regarding creation responsibility, "it is required, for electromagnetic records, to devise a process that confirms the presence of the fact of modification or erasure made within their legally required storage period and its contents and to clarify the responsibility for the creation of those electromagnetic records." (The ministerial ordinance regarding the use of telecommunication technologies for the preservation of documents, as done by private enterprises, is based on the regulations of the Ministry of Health, Labor and Welfare. Article 4 Clause 4.2, March 25, 2005.) The ministerial ordinance regarding the use of telecommunication technologies for document preservation by private enterprises is based on the regulations of the MHLW.

At medical institutions, image information obtained from an imaging device or modality for use as grounds for diagnosis is stored in information systems such as PACS; the act of storing this information is effectively the KAKUTEI operation, and the person who carried it out is responsible for the image information's creation. For example, if a radiological technologist carries out imaging examination and stores the image information in PACS as "image information legally subject to storage," the radiological technologist is responsible for the creation of the image information as the person who performed its KAKUTEI and storage operations. Moreover, it is the duty of the person responsible for creation to confirm before

storing the information that it has been correctly created and entered and that there has been no rewriting, erasure, or confusion.

To be certain of these operations, carried out before the act of KAKUTEI, it is not necessarily required to retain a history of these operations. In addition, creation responsibility also occurs for rewriting and erasure operations after KAKUTEI; however, if the change is only for temporary display (such as changes in density or magnification) and there is no change in the originally stored image data, then incremental KAKUTEI and storage are not required.

In order to clearly present creation responsibility, it is necessary to clarify the person responsible for creation, and to devise a way to promptly present this information electromagnetically or on documents when required.

3.2.1. Cases involving image processing

Image information whose authenticity is to be secured is considered confirmed (or “KAKUTEI-ed”) and the image information preceding the confirmed records is not subject to the provision of authenticity.

For example, if a radiological technologist processes a 3D image and KAKUTEI-then-stores the processed image information in PACS, and a physician performs a diagnosis using this image information, then the image information used to make the 3D image (i.e., thin-slice images) are not objects of storage. In this case, the person responsible for creation is the radiological technologist who stored the processed image in PACS (Q & A in the MHLW security management guideline v. 4.3, Q42).

Moreover, regarding the 3D images, the Q & A of the MHLW security management guideline v. 4.3 specifies:

> **Q:** "For an x-ray CT, I use the original image and 3D images created from the original images for diagnoses. Is it allowed, with electronic [storage], to delete the 3D images used for the diagnoses as long as I save the original images? It is difficult to reproduce the 3D images completely because the parameters are not stored."
>
> **A:** "There is no need to save processed image information used directly for the diagnoses and clinical services, provided their reproduction is, in principle, possible. In this case, however, because it is difficult to reproduce the 3D image used for the diagnoses completely, the 3D image should not be deleted."

3.2.2. Recording the personnel responsible for creation

It is necessary to specify, in the policy and procedure manual, where the record of the person responsible for image information creation is stored. Records of persons responsible for creation are not always supplemental to the image information; they can be noted in other systems or on paper documents.

For example, the following stipulation can be considered: "for CT images, one who performed the examination as recorded in the RIS (Radiology Information System) is the person who operated KAKUTEI of the examination."

3.2.3. Cases without explicit KAKUTEI operations

To clarify the personnel responsible for creation of a record, certain operational cases assume that it is KAKUTEI-ed, even without an explicit KAKUTEI operation. In practice, such cases include those in which image information is automatically sent from the imaging modality to PACS and saved, at which time the image information is considered to be KAKUTEI-ed, or in which the image information is considered to be KAKUTEI-ed at a specified time of day or after a pre-defined amount of time has elapsed. In such cases, it is necessary to establish a method for specifying the personnel responsible for creation, as well as operational methods, and it must be clearly documented in the policy and procedure manual.

For example, if the policy and procedure manual states that " image information sent automatically from the CT to PACS is KAKUTEI-ed at midnight on the same day, and the person responsible for creation is so-and-so," this person is responsible for the appropriate storage of such image information. If additional notes, overwriting, or erasure become necessary, this content must be created as new information in association with the KAKUTEI-ed image information and KAKUTEI-stored as such. In this case, the person responsible for creation is the one who carried out the operation.

3.2.4. Time synchronization

It is necessary for records to contain the date and time of creation based upon a reliable reference time. A reliable reference time needs to be periodically synchronized with the standard time such that the accuracy maintained is adequate for recording clinical services. At medical institutions, medical and diagnostic imaging devices (hereafter referred to as modalities) and PACS, at the least, must be time-synchronized. It is not mandatory to deploy a system such as a time server.

3.2.5. Electronic signatures

Electronic signatures, according to the Law Concerning Electronic Signatures, must verify two points: that the information has been created by the signer and that the information is not altered. These two verifications are required for electronically preserving documents that require signatures (sign and seal) by law.

While it is possible to prove that the author and documents have not been tampered with, the time-stamp policy verifies this with the time of creation. With a time-stamp, it is proven that the document actually existed at the time of the stamp, as synchronized with standard time, independent of the embedded clocks of individual information systems, and that no manipulation was made afterward.

Verifications from reliable third parties—a certificate authority and time-stamp station—is needed for electronic signatures and time stamps, respectively. Although these methods are useful for establishing trust with external parties, applying them to documents that require less verification may affect daily operations.

For the electronic storage of image information, it is necessary to clarify the personnel responsible for its creation and to appropriately record the date and time of KAKUTEI. However, it is not mandatory to perform electronic signatures or time stamps as indicated in the Law Concerning Electronic Signatures, and it would suffice to record them with image information systems, medical information systems, or with their application software.

4. Handling film copies and image information from external institutions

At medical institutions, image information obtained from examinations and thereafter KAKUTEI-stored must be properly managed, including the recording of the personnel responsible for creation. Lately, collaboration among medical institutions for the provision of medical care to patients has become common practice, and there are many cases in which image information is supplied from external medical institutions. As such, storage and management obligations related to this image information must be clarified.

4.1. Storage obligations

Clearly, the results of imaging examinations performed at an external institution must be properly retained by the external institution itself. If the external image information is used for making diagnoses or therapy plans, and in cases in which such decisions are noted in the medical record, it may become necessary to record this image information as the basis of these decisions. In addition, in the case of clinical information sharing for the provision of care to patients, the institution that initiates the sharing of image information will have purposes such

as seeking out a diagnosis that warrants greater expertise or requesting consultation regarding treatment Guideline. Therefore, it might be necessary to store the image information as grounds for accountability for the receiving institution.

In these cases, the image information used as grounds for diagnosis must be stored.

Image information can be brought into a medical institution through various means, such as by network or portable media. For the "form of image information provision," the Health Information and Communication Standards (HELICS) Board has published a standardization guideline, "HS009 IHE Integrated Profile: Portable Data for Imaging Integration Profile and Its Application Guideline."

4.2. Handling portable media from external institutions

Portable media brought into a medical institution belongs to the patient and does not necessarily need to be retained by the referred medical institution. When discarding portable media, MHLW security management guideline 6.7, "Discarding information" must be followed.

4.3. Importing image information and creation responsibility

It is necessary to clearly document the assignment of responsibility pertaining to image information imported from external medical institutions in the policy and procedure manual. In general, the person who imported the image information to PACS is responsible for its creation. In addition, when supplemental information is modified, this action needs to be recorded but not necessarily electronically recorded.

5. Conditions for film digitization

If medical records such as films are received, stored, or handled, followed by their digitization, the MHLW security management guideline, Chapter 9, "Electronic storage of paper-based clinical records with an image scanner," must be followed.

5.1. Films as objects of storage

Most frequently, film digitization is carried out for handling convenience and the films are retained in their original state. In this case, the digitized information is reference information and not subject to storage obligation. For the purposes of authenticity and proper storage, it is quite effective to preserve the original films. However, the protection of personal information must be treated in the same way as for content whose storage is required. In addition, it is important to ensure that digitization precision is sufficient for clinical services. The Japan

Radiological Society (JRS) has provided, "The guideline for handling digital images v. 2.0," which defines the precision required for scanning.

Digitized images should be stored in DICOM format to avoid incompatibility with visualization software. The policy and procedure manual must establish guideline for proper digitizing methods.

5.2. Electronic information as objects of storage

Examples of digitized information as objects of storage are presented in the following two scenarios.

- When clinical services are mostly carried out with electronic documents through utilization of tools such as electronic medical records, the case in which papers or films from external medical institutions are shared for care provision. These cases are discussed in Section 5.2.1.
- Upon introduction of systems such as electronic medical records, prior records remain in hard copy and consistent information handling cannot be performed. Alternatively, there is not enough space to store the paper documents. These cases are discussed in Section 5.2.2.

In either case, electronic storage should only be carried out if the co-existence of electronic information and films causes major information handling problems.

5.2.1. Image information storage by digitizers at each point of care

In addition to the conditions stated in Section 5.1, the following operational conditions must be met: (i) the equivalence of information between digitized images and films is verified and a manager for information creation and operations is put in place to ensure that handling is carried out appropriately; (ii) the person responsible for record creation (executor or manager) must establish electronic signatures and time stamps as per the law and in a timely manner, clarifying responsibility for the records. For electronic signatures, the MHLW security management guideline 6.12, "About making electronic signatures for signs and stamps required by law," must be followed; and (iii) film digitization is completed within a set period of time upon receiving the film. This period of time should be one to two days, as set forth in the policy and procedure manual, and should not hinder clinical services.

5.2.2. Electronic storage of previously accumulated films by digitizers

We do not recommend this situation in this guideline. In addition to the methods indicated in Section 5.1, most purposes should be met by externally storing films. If an explicit decision is made to carry out this operation, a number of actions are required in order to ensure accountability. That is, upon meeting all of the conditions indicated in Section 5.2.1., it is necessary to obtain patient consent in advance and conduct a rigorous audit. The MHLW security management guideline 9.3 requires the following steps: (i) provide notice to and gain prior consent from patients, (ii) develop an action plan and evaluate its validity by a committee consisting of both internal and external knowledgeable persons, and (iii) an audit by an external agent with adequate capabilities.

6. Retention period and compression of image information

Image information legally belongs to "other records of clinical services." The Medical Care Law Enforcement Regulations Article 20 requires two years of retention, and Article 9 of the regulations for medical institutions and medical training institutions requires three years of retention from the day of the conclusion of the clinical service. Moreover, for medical records, Medical Practitioners' Act Article 24, Dental Practitioners Law Article 23, and the regulations for medical institutions and medical training institutions Article 9 require five years of retention.

Image information must be stored in the same condition as viewed for interpretation. If a diagnostic reading is made with a lossless compression image, it must be stored in this way and not with lossy compression. While the aforementioned requirement may not apply for image information whose age has passed legally required retention period, handling must be otherwise be documented in the policy and procedure manual.

For example, image information is stored with lossy compression five years after the conclusion of the clinical service. Nonetheless, this is not applicable if such handling would cause any disadvantage to the patient.

7. KENZO

KENZO refers to actions carried out by radiological technologists to assist physicians in interpreting images and making diagnoses, such as verification of appropriate images, correction of images as necessary, or deletion of unnecessary images, before confirmation (or KAKUTEI) of those images. The points to be verified before KAKUTEI include whether the acquired image information is in accordance with the exam order and whether supplementary information was correctly entered. Additionally, modifications in supplementary image

information, image density, image direction, and the sequence of images should be corrected as necessary.

KENZO does not require special devices, equipment, or application software; it can be comprehensively carried out by striking a balance between the technical and operational needs. Each medical institution should, upon judging their scale, department systems, and characteristics, consider the most effective actions.

7.1 Types of information to be verified

A sample of information requiring verification while conducting KENZO is summarized in Table 1.

Patient information	Patient ID
	Patient name
	Age
	Sex
Exam order information	Ordering Department
	Ordering Physician
	Content of examination
	Purpose of examination
	Date and time of examination
Image information	Modalities
	Number of images
	Number of series
	Sequence of images
	Body part to be examined
	Extent of examination
	Direction of images
	Image density
	Contrast
	Image quality
	Marking
	Other handling

※Direction of images: top, bottom, right, left, anterior, posterior

※Image quality: image blurring, sharpness, etc.

※Other handling: filter, MIP, MPR, 3D, etc.

7.2 Cases of KENZO Operations

We list a few cases of KENZO below, but each institution may deploy a combination of these operation types or various others for different imaging modalities. In addition, KENZO operations do not have to be performed by technological means alone and can be carried out operationally. For example, a cross-check of patient information can be performed either by automatically collating it between one copy transmitted from Radiology Information System (RIS) to KENZO application software and another contained in the image information, or by manually cross-checking it between a copy viewed on an RIS display or hard copy and another displayed on an image viewer.

7.2.1. Case 1: KENZO operated at imaging modalities

In this case, KENZO is performed at an imaging modality through which exam images are taken. With or without KENZO application software, KENZO operations are performed at the modality. KENZO-completed images are then sent to a storage device for electronic storage.

7.2.2. Case 2: Specialized software applications for KENZO

This case involves sending images from the imaging device to a KENZO-dedicated system and carrying out KENZO operations with specific KENZO application software. KENZO-completed images are then sent to a storage device for electronic storage.

7.2.3. Case 3: KENZO using Image Viewer as a PACS functionality

Images from an imaging device that are stored in PACS are retrieved to Image Viewer, in which KENZO is performed, and then sent to a storage device for electronic storage. With or without KENZO application software, KENZO operations are performed in Image Viewer. If the storage device contains images before and after KENZO, it is necessary to distinguish between the two images and ensure that the post-KENZO image is not deleted by mistake.

8. External storage, backup at external facilities, and sharing within regional medical collaboration of clinical image information

There has been confusion regarding the external storage of image information, backups at external facilities, and sharing within regional medical collaboration. This section explains requirements that relate to each of the aforementioned cases respectively.

8.1 External storage

In this guideline, external storage means to store and operate clinical records legally subject to storage outside of the medical institution, while meeting the three principles of electronic storage in the MHLW security management guideline. If a loss in readability occurs because of external storage, it is necessary to store those records within the institution under conditions meeting the three principles of electronic storage.

In addition, for securing the readability of externally stored records through networks, the MHLW security management guideline indicates that it is necessary to store medical records and information anticipated to be needed urgently within the institution or maintain copies of equivalent information internally while they are stored externally. The MHLW security management guideline also indicates that it is necessary for medical institutions to prepare for network trouble or failures at the external storage institutions to which information is entrusted, even if it may not be urgently needed.

8.2. Backups at external facilities

There are following two types of external data backups: (i) medical record backups, made in preparation for loss of medical records and (ii) disaster recovery backups designed for continuity of clinical services in times of disaster. Because the two types differ in purpose, they naturally differ in data volume and structures, the timing of backup data acquisition, and legal requirements.

For medical record backups, although the provision of authenticity, the provision of visual readability, and the provision of storage property are not required for backup data themselves, it is obvious that criteria equivalent to those of medical records are required at the time of restoration. In addition, when restoring, it is important to prove that a document is restored. When contracting with service providers, it is necessary to add this proof in the agreement.

Conversely, for disaster recovery backups, there are no such legal requirements. Each community or institution should determine the data items necessary for disaster backup according to their purpose.

8.3. Sharing within regional medical collaboration

In this section, data refer to those accumulated for external storage or backups. Therefore, when making secondary use of those data for regional medical collaboration or medical research, it is necessary to take adequately intricate steps.

The sharing of information by multiple medical institutions requires a patient's consent, and while external storage or backups may be needed for medical institutions to fulfill their own responsibilities, it is a misunderstanding to presume that those externally stored or backed-up data can be shared without taking appropriate measures.

When using data for regional medical collaboration, it is necessary to establish operational mechanisms, such as the acquisition of patient consent, policy agreements between participating institutions, clearly defined shared information and access rights management, understanding of each institution's scope of responsibility, and provisions for interoperability (refer to the appendix of the MHLW security management guideline).

In addition, for image information, there are conceptual differences between KAKUTEI at a medical institution that provides such image information in the context of regional medical collaboration, and the “retention of data as grounds for diagnosis” at another medical institution where diagnosis is made based on the provided image information (refer to Section 4.1 for storage obligations in such cases).