Exemption Request Form

Date of submission: 6th January 2020

1. Name and contact details

1) Name and contact details of applicant:

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This exemption application is submitted with the endorsement of the business associations listed below:

Japan Analytical Instruments Manufacturers' Association (JAIMA)	Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA)	The Japan Federation of Medical Devices Associations (JFMDA)
Japan Inspection Instruments Manufacturers' Association (JIMA)	Japan Medical Imaging and Radiological Systems Industries Association (JIRA)	Japan Measuring Instruments Federation (JMIF)

2. Reason for application:

Please indicate where relevant:

☐ Request for new exemption in:

☐ Request for amendment of existing exemption in

☒ Request for extension of existing exemption in Annex IV

☐ Request for deletion of existing exemption in:

☐ Provision of information referring to an existing specific exemption in:

☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: 1 of Annex IV

Proposed or existing wording: cadmium in detectors for ionising radiation

Duration where applicable:

Maximum validity period of 7 years

That is;

- Category 8 and Category 9 except monitoring and control instruments in industry : July in 2028
- Category 9 monitoring and control instruments in industry : July in 2031

☐ Other: _____

3. Summary of the exemption request / revocation request

By the transmission ability, X-rays and gamma rays are utilized to see inside the human body or objects in the field of medical diagnostics, non-destructive testing, food inspection, baggage screening and so on. For these applications, the following 4 technical requirements are crucial for the radiation detectors.

- High sensitivity

Higher sensitivity of the detector enables reduction of radiation dose, leading to lower risk of the patient, medical staff and operators. This is critical for the citizen's human health.

- High spatial resolution

High spatial resolution is an ability to see the fine object clearly, and this is the fundamental function of the "imaging detector" to find the small pathological change of the patient, abnormality of the object, contaminations of the foreign substance, explosives in the baggage and so on.

- High energy resolution

Japan Business Council in Europe

The energy information of the radiation can give the new additional functions to the radiation imaging. It is used not only for removing the scattering ray to improve the image quality, but also for material discrimination ability by the multi-energy imaging.

- Room temperature operation

If the detector cannot be operated at room temperature, it requires the cooling system and the whole device size becomes too large or the device cannot be realized. It is practically very important.

Cadmium telluride (hereafter CdTe) or cadmium zinc telluride (hereafter CZT) detector meets the above 4 technical requirements and used for category 8 and 9 applications, contributing to the society, such as human health, safety of the plant, reliability of the products, security at the border and so on.

The above 4 technical requirements should be considered to search for the alternative detector of CdTe and CZT.

An indirect conversion type detector using the scintillator has lower spatial resolution due to the spreading of the scintillation light in principle. Therefore, the alternative of CdTe or CZT is limited to the same direct conversion type using the semiconductor material.

So far only a few semiconductor materials, such as silicon (Si), amorphous selenium (a-Se), germanium (Ge), CdTe and CZT have been used as the direct conversion type detectors and some other semiconductors are the new candidates. However, only CdTe or CZT can satisfy 4 important requirements and there are no alternatives of them so far.

If this exemption is expired, the medical diagnosis will become poor and the radiation exposure risk to the patient or the medical staff will increase.

This technology of making invisible object visible can contribute to the society very much, so depriving the society of this technology will cause a huge negative impact rather than the environmental merit. Therefore, we apply for the renewal of this exemption.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

   Name of applications or products:

Medical diagnostic devices using X-ray or gamma ray of category 8, such as, X-ray CT(1-2), Bone densitometry(3-4), mammography(5-8), angiography, X-ray radiography, dental X-ray imaging devices(9), X-ray colorectal capsule camera(10-14), scintigraphy, SPECT(15-18), PET(19-21), gamma probe(22-23) and so on

Monitoring and control instruments including industrial monitoring and control instruments using X-ray or gamma ray in category 9, such as Non-destructive testing system(24), industrial pipe/plant inspection system(25-27), food inspection system(24), X-ray diffractometer(28-29), X-ray fluorescence spectrometer (XRF), level checker for bottling, gamma-ray imager for radioactive pollution(30-31), gamma ray spectrometry, small animal CT, baggage scanner*(32-35), explosive detection system*(38-40) and so on.

*; baggage scanner, explosive detection system used for protecting the essential interest of the security of the Member State are out of scope of RoHS by the article 2, 4(a).

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☒ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

   The requested exemption will be applied in

   ☒ monitoring and control instruments in industry

   ☐ in-vitro diagnostics

   ☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?
   (Indicate more than one where applicable)
   ☐ Pb ☒ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: Cadmium is the major element of the cadmium telluride and cadmium zinc telluride as the semiconductor radiation detector, which detects the ionising radiation.

4. Content of substance in homogeneous material (%weight):
   In case of cadmium telluride (CdTe), cadmium is 46.8% of CdTe
   In case of cadmium zinc telluride ($Cd_{(1-x)}Zn_xTe$), it is changed by zinc concentration x. If x=0.1, cadmium is 43.0%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: cadmium 600kg per year
   Please supply information and calculations to support stated figure.

   Quantity of cadmium is from study carried out for the European Commission on the possible inclusion of categories 8 and 9 in scope of RoHS in 2006(41) and assumes that the amount of 300kg has doubled since 2006.

6. Name of material/component:
   Cadmium telluride (CdTe) and cadmium zinc telluride ($Cd_{(1-x)}Zn_xTe$) semiconductor detector for ionising radiation.

7. Environmental Assessment:
   LCA: ☐ Yes
   ☒ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Cadmium is included in CdTe or CZT semiconductor radiation detector, which detect X-ray and gamma ray. The detector is used for the applications listed in section 4. (A).1.

The application listed in section 4. (A).1 belong to two categories, category 8 ; medical devices and category 9; monitoring and control instruments, however, the applications in both categories are based on the same scientific principle and have the same objective, which is making invisible objects visible clearly. Therefore, category 8 and 9 are essentially the same from this point of view. As this technology contributes to society in various applications and CdTe or CZT radiation detector is the most suitable material for the application, we hereby request this renewal of the exemption.

The technical reasons for the renewal request are described as follows;

-The principle of the CdTe, CZT semiconductor radiation detectors

For better understanding, the operation principle is described at first.

The schematic of the CdTe radiation detector is shown in Fig.1 [42]. The electrodes are formed on both sides of the high resistivity CdTe or CZT semiconductor crystal and the high bias voltage is applied on the electrodes, forming the electric field in the crystal. When a irradiated photon such as X-ray or gamma ray is absorbed in the crystal, it generates the electron-hole pairs. Then, the electrons and the holes are driven by the internal electric field to the anode and the cathode electrode, respectively. Through amplifying the electrical charge in the readout circuit, the photon can be detected. If the photon passes the crystal without being absorbed, electron-hole pairs are not generated and nothing can be detected. Therefore, the detector needs the high absorption capability of the photon for the high sensitivity. The high atomic number of the constitutional element and the high density are needed for the high absorption.

As the number of the generated electron-hole pairs are proportional to the energy of the absorbed photon, the photon energy can be identified. By distinguishing the photon energy one by one, the frequency distribution of the photon against its energy can be plotted, which is the so-called energy spectrum. The example of the energy spectrum measured by CdTe detector[43] is shown in Fig.2. The ability to measure the energy of photon precisely is called energy resolution, which is usually evaluated by the full width at half maximum (FWHM) of the peak in the energy spectrum. This energy resolution is determined mainly by the mobility–lifetime products (μτ products) of the semiconductor. The larger μτ products means that the charge carrier can drift longer distance without being trapped inside the detector. CdTe or CZT has large μτ products and good energy resolution at room temperature.

The bandgap energy is also an important factor as the semiconductor radiation detector. If the bandgap is not high enough, electrons in the valence band are easily activated to conduction band due to the thermal energy and the leak current increases. This leak current becomes the cause of the noise. Therefore, if the bandgap energy is not high enough, the detector performance at room temperature is deteriorated by the noise, and in order to avoid it the cooling of the detector is required. The bandgap energy of the CdTe and CZT are so large that the detector can operate at room temperature without cooling.

Therefore, atomic number of the element, μτ products and the bandgap energy are very important factors to decide the performance of the semiconductor detector. These parameters are discussed in section 6 later.

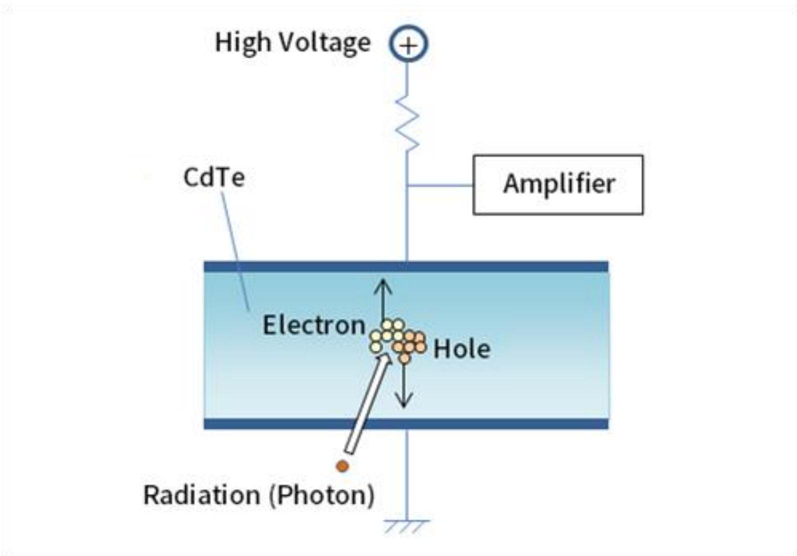


Fig.1 The principle of the CdTe semiconductor radiation detector (42)

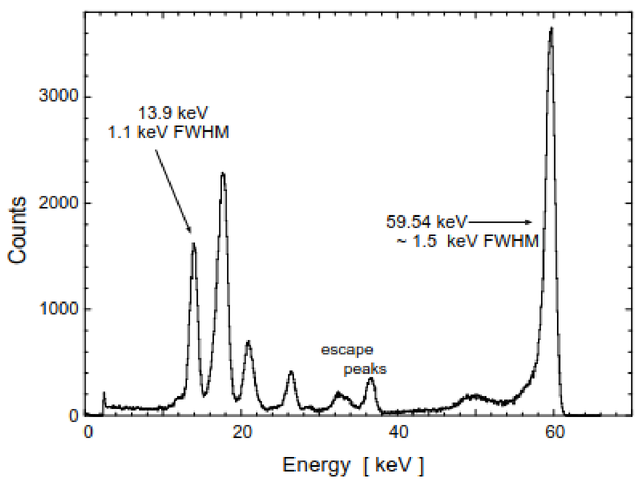
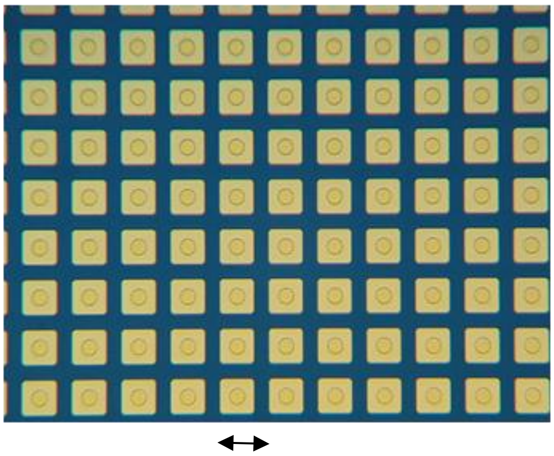


Fig.2 Energy spectrum of the gamma ray source ^{241}Am taken by the CdTe radiation detector (43)

(a) Radiation imaging

By arranging the plural small radiation detectors in lines and rows to form the array of the detector, or by forming the divided electrode on the CdTe surface as shown in Fig.3, so-called pixel electrode, the two dimensional image of the radiation can be obtained. Each individual small detector or each pixel electrode is the picture element of the image. This kind of detector is called “flat panel detector”, or simply FPD.



Pixel pitch 0.1mm

Fig3. Pixel electrode formed on the CdTe surface

Fig.4 shows how the X-ray image is obtained. X-ray is generated by the X-ray tube and irradiated to the object. The X-ray absorbed in the object is varied by its thickness and material inside the object, and the two dimensional distribution of the X-ray at the detector is obtained. One dimensional array detector, that is called “line sensor”, can also obtain the two dimensional radiation image by moving the object against the line sensor or moving the line sensor against the object. FPD and line sensor are generically called Digital Detector Array (hereafter DDA).

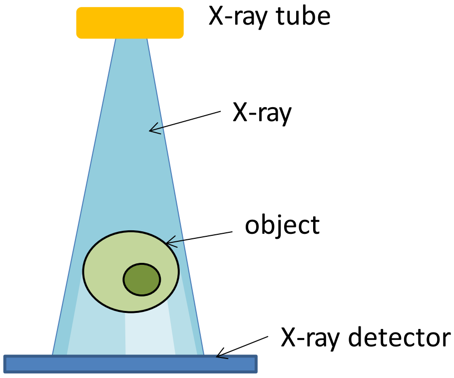


Fig.4 The method to obtain X-ray transmission image

The applications such as X-ray radiography, bone densitometry, mammography, angiography, dental X-ray diagnostics and so on are the typical examples in medical application field. Fig.5 shows an example of dental panoramic image taken by the CdTe line sensor[9].

Also the tomogram of the object can be obtained by taking many image data by rotating the X-ray tube and the X-ray detector around the object, followed by computing the data numerically, which is X-ray CT[1-2].

In cases where the object is a mechanic/electric part, the system is called non-destructive testing system, in cases where the object is the pipe line or chemical plant, it is called pipe / plant inspection system[25], in cases where the object is food, it is called food inspection system, in cases where the object is baggage, it is called baggage scanner[32-35] or explosive detection system[38-40].

In scientific field, X-ray diffraction pattern is obtained in the similar configuration but X-ray is collimated to the narrow beam and diffraction spots are observed by DDA, which is used for determining the crystal structure of the sample[28-29].

These applications above require high spatial resolution. In any applications the clear image of the fine object is crucial for the diagnosis and inspections. The image taken by DDA using CdTe or CZT is clearer than that taken by scintillators (indirect conversion type). This is elaborated in section 6.

The high sensitivity of the detector is also important, because it can reduce the radiation dose. This is especially important in medical applications, because the radiation dose to the patient and medical staff is the negative side of the radiation imaging. This is the same in the applications of category 9 applications, since it reduces the risk of the radiation exposure to operators. CdTe or CZT has high sensitivity and can obtain the clear image with low radiation dose.

Fig.5 Dental panoramic image taken by CdTe pixel detector [9]

(b) Utilizing the energy information of photon

In case of nuclear medicine applications such as Scintigraphy, SPECT, PET and gamma probe, an isotope labeled medicine is injected into the patient, instead of the X-ray irradiation. The medicine is accumulated in the specific tissue and the gamma ray is emitted from it.

Fig.6 shows the example of the scintigraphy or SPECT[15-18]. The gamma ray is emitted to all directions from the tissue where the isotope labelled medicine is accumulated. The gamma ray directing to the detector makes the image of the tissue. While the gamma ray directing to the other direction should not make the image, but it is scattered by the surrounding tissue and it is possible to enter the detector. The position where the gamma ray is scattered worked as if the isotope labeled medicine is accumulated there, so the image of the tissue becomes blurred by this artificial tissue caused by scattering. However, as the energy of the scattered gamma ray is decreased, it is possible to distinguish the scattered gamma ray from the gamma ray directly emitted from the isotope by using the photon energy information. Therefore, the clearer tissue image can be formed using gamma ray only within the limited energy range (energy window) to remove the scattered ray. So the detector with high energy resolution is preferable. In addition to that, it is also possible to use two isotope nuclides simultaneously and the efficient diagnosis becomes possible. CdTe or CZT detector have the high energy resolution for this purpose.

For nuclear medicine application, the sensitivity of the detector is also important. As the gamma ray flux emitted from the isotope medicine is much lower than the X-ray irradiation, imaging needs a long time. The patient is forced not to move for twenty to thirty minutes. If the sensitivity is high enough, the imaging time can be reduced or the dose of the isotope medicine can be reduced.

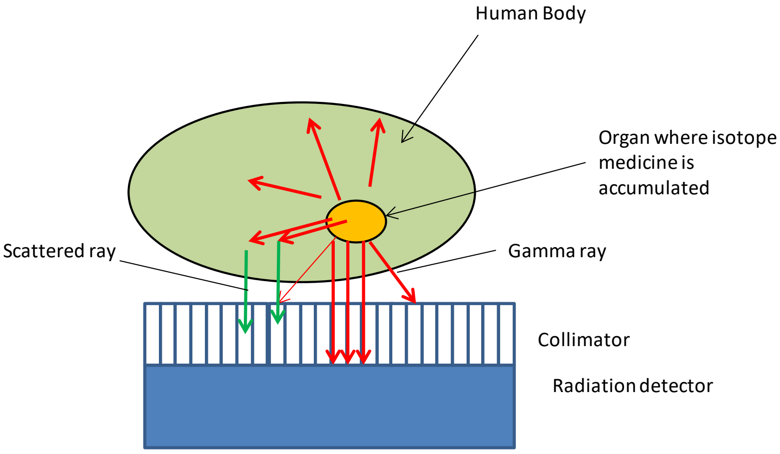


Fig.6 Example of Scintigraphy or SPECT

The gamma cameras[30] [31] for imaging the environmental radioactive pollution have been developed, their principle is the same as scintigraphy. They are quite useful for recovering the environment from the radioactive pollution, for instance, caused by the severe accident of the nuclear power plant. It is required to detect the high energy gamma ray with low count rate and determine the radioactive nuclide. Therefore, high sensitivity and high energy resolution is necessary. CdTe and CZT is the suitable materials for this purpose because of the high sensitivity and high energy resolution at room temperature.

X-ray irradiated from the X-ray tube is composed of the photons with the various energies as shown in Fig.7. If the acceleration voltage Vp is 100kV, the photon energy is distributed in the range of less than 100keV. As the transmission ability of the X-ray depends on both the photon energy and the material of the object, it is possible to discriminate the material of the object using the images data taken at different X-ray energy. For the example of Fig.7, if the detector can distinguish the photon energy, 5 transmission images using the 5 different energy range are obtained simultaneously, to discriminate the object material.

The diagnosis of bone density by the dual energy x-ray analysis (DEXA) bone densitometer[3-4], photon counting CT[1-2] using the multi energy, food inspection system using the dual energy subtraction method(44-45), Pipe/plant inspection system(25-27), explosive detection system(32-35,38-40) are the application examples. As they need both high spatial resolution and high energy resolution, CdTe or CZT detector is used for these applications.

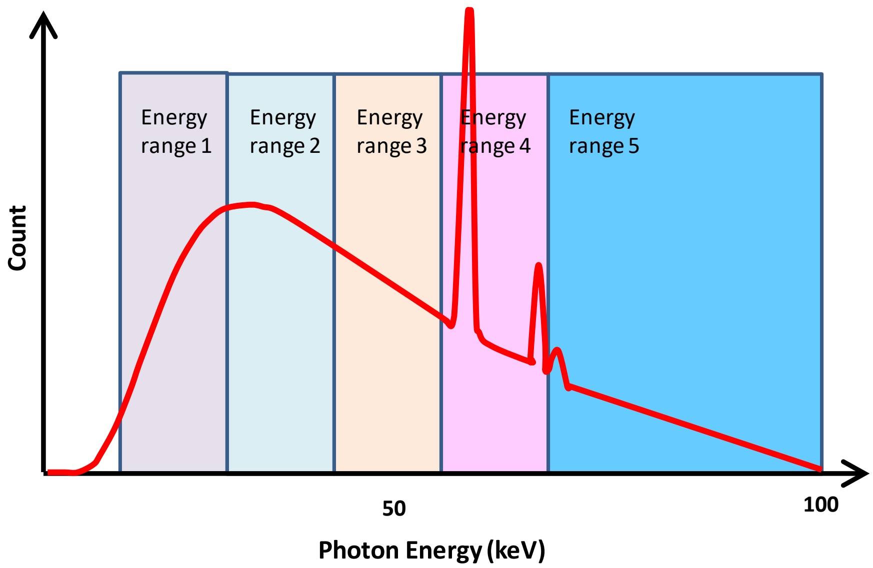


Fig.7 Energy Spectrum of X-ray, example of Vp=100kV

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The most important characteristics of the radiation detectors listed in section 4(A).1 are the following 4 requirements.

(1) High sensitivity

The detector must have the high sensitivity, otherwise the radiation dose to the object would be inevitably increased. This is crucial for the medical application, as the radiation exposure to the patient is one of the root-causes of the cancer. The exposure to the medical staff around the patient during the operation is also problematic, therefore, reducing the dose is important for medical staff, too. If we cannot use the detector with high sensitivity, it would be an irreparable negative impact on the health of the citizen.

For non-destructive testing applications and food inspection, if the sensitivity of the detector is low, X-ray flux would be inevitably increased or the inspection speed would be inevitably decreased. The life time of the X-ray tube is shortened by increasing the X-ray flux. By decreasing the inspection speed, more inspection lines are needed. As a result, inevitably the inspection cost increases by using the low sensitivity detector. It will have a negative impact on the EU industries and citizen.

For scientific applications, X-ray diffraction method is used to reveal the crystal structure of the samples. If the detector sensitivity is not high enough, the weak diffraction spot cannot be obtained and the information on the crystal structure is decreased. Otherwise, the measurement time needs to be increased. Some type of the sample is deteriorated by the larger dose. Therefore, the detector with high sensitivity is necessary.

Regarding the well-used energy range of category 8 and category 9 applications, CdTe or CZT has sufficient absorption ability. They have much higher sensitivity than the traditional silicon detector or germanium detector.

(2) High spatial resolution

High spatial resolution is a fundamental requirement for the imaging detector.

In medical applications, the lesion in body should be found as small as possible. If the detector with high spatial resolution should not be used, the healthcare of the EU citizen is deteriorated.

In non-destructive testing applications, the high spatial resolution is also important. For example, wire-bonding in the IC chip is checked by X-ray flat panel detector[46]. It is required to detect the abnormality of the gold wire of only 0.03mm diameter. Electronic parts are getting smaller and smaller, so the spatial resolution should be improved as much as possible.

In food inspection, as we can feel 0.1mm large foreign substance in food, such a small object must be detected. As the flow-out of the contaminated food into the market directly affect the citizen’s life and health, utilizing the detector with highest spatial resolution is important.

(3) High energy resolution

As already described, the nuclear medicine applications like scintigram, SPECT[15-18] and gamma probe[22-23] make the image of gamma ray within the energy window to remove the scattered ray. If the detector has higher energy resolution, sharper image can be obtained by using the narrower energy window as in Fig.8. If the narrow energy window is used for the detector of the low energy resolution, the count rate becomes small and the measurement time becomes longer. On the other hand, wider energy window cannot remove the scattering ray, resulting in a blurred image.

X-ray imaging applications, such as bone densitometry, photon counting CT, non-destructive testing, food inspection, baggage scanner and explosive detection system utilize the images of the several energy ranges as described in Fig.7. By calculating the image data of the several energy range, extracting or removing the image of specific material and also material discrimination become possible(24,32-37).

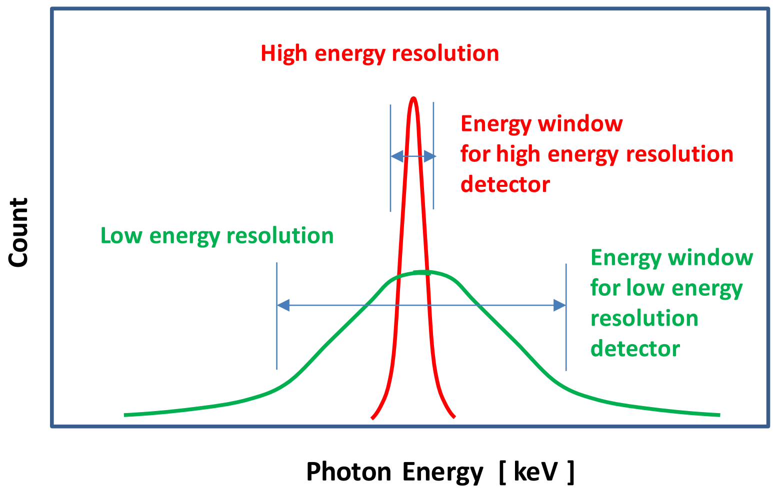


Fig.8 The schematic of the relation between energy resolution and energy window.

The traditional X-ray imaging technology doesn't use the energy information and make one image through the full X-ray energy range. This is like the black and white photograph, which doesn't distinguish the color (energy) of the light. As a result, the information of the original color disappears. On the other hand, color film can record the color information. Similarly, X-ray images of the different energy range can be taken if the detector can distinguish the photon energy one by one. These images give the information of the material.

For an example of the food inspection, if the thickness of the object is varying, it is difficult for the traditional "Black and white" x-ray imaging to distinguish the foreign substances in the food because not only the foreign material but also the thickness change cause the similar contrast difference. However, by using the data of two energy ranges, extraction of the foreign substances from the food is possible. This is called 'dual energy subtraction method'(44-45).

For an example of the pipe inspection, the pipe used for the chemical plant is usually surrounded by the thermal insulator and it causes the corrosion over time. Therefore, the periodical inspection of the pipe is necessary for the safety operation of the plant. Visual check or ultrasonic inspection has been carried out after removing the thermal insulator. This has been a quite inefficient method. However, the pipe without removing the thermal insulator or the pipe with liquid inside is now able to be inspected precisely by using the x-ray image data of several energy ranges because the multi energy imaging using the CdTe detector can remove the thermal insulator or the liquid in the pipe and generate the naked pipe itself(26-27).

In case of the X-ray fluorescent (XRF) analysis, high energy resolution is necessary to identify the peak energy of the characteristic X-ray.

(4) Operation at room temperature

For the practical applications, the detector should operate at room temperature. If the detector works only at lower temperature than the room temperature, the device needs the cooling system and the size of the device becomes large, or the device cannot be realized. Also it would be difficult to operate outdoors if it needs the cooling.

CdTe or CZT has superior characteristics compared to the other detectors in terms of the above 4 requirements. Therefore, they have been used for the applications described in section 4. (A).1 and the new application device are being developed. The comparison with the other detector materials are carried out in section 6 briefly. However, in short, there are no other materials than CdTe or CZT, satisfying the 4 requirements.

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5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

Detectors for ionizing radiation are installed for inspection equipment which is used in special fields such as medical device in hospital, non-destructive testing, food inspection and security related issue. The equipment requests high level technical requirement and is treated by “Professionals” during their whole lifetime.

According to WEEE directive requirement, the equipment shall be collected by the responsible company which is in the WEEE registration list and passed to the Recycler who shall treat them adequately under the WEEE requirement.

In case of expensive medical devices such as CT, SPECT and PET, they can be refurbished or reused.

2) Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse

☒ Article is collected and dismantled:

- ☒ The following parts are refurbished for use as spare parts: CdTe /CZT detectors which can be reused
- ☒ The following parts are subsequently recycled: CdTe / CZT detectors which cannot be reused

☐ Article cannot be recycled and is therefore:

- ☐ Sent for energy return
- ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☒ In articles which are refurbished cadmium 480 kg (assumes 80% of detectors can be reused)

☒ In articles which are recycled cadmium 120 kg

☐ In articles which are sent for energy return ______

☐ In articles which are landfilled ______

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Radiation imaging detector

The radiation image was taken originally by analogue film, then it has been changed to the digital method using DDA including FPD. As the sensitivity of the film is very low compared to the current DDA, much higher radiation dose was necessary. The image was kept by the film and it needs the wide stock area. For sharing the image with someone else it was necessary to send the film itself. The digital image processing is very useful technology but analogue film was not suitable for that. Therefore, DDA has become main stream in radiation imaging technology.

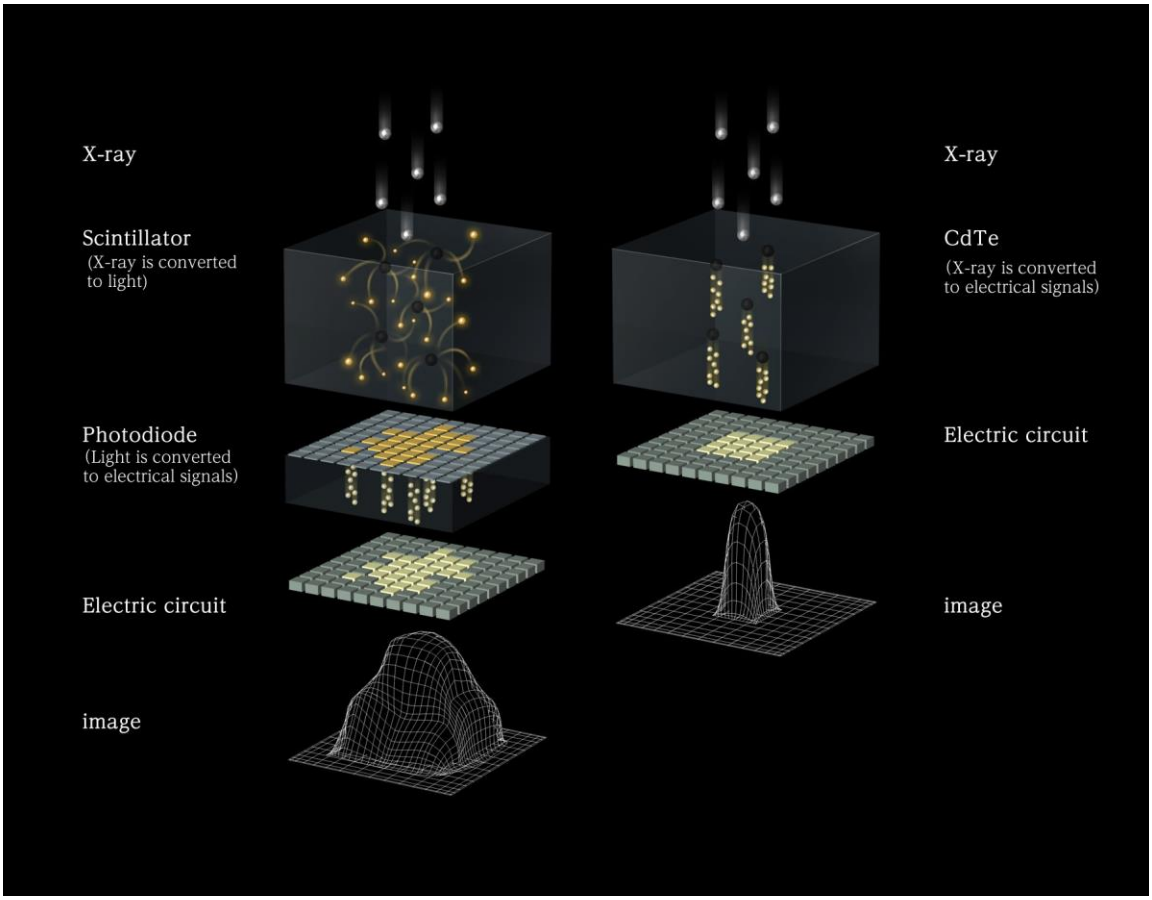

Fig.9 The difference of indirect conversion type (left) and the direct conversion type (right) [42]

There are two types of DDA, an indirect conversion type and a direct conversion type. Fig.9 shows the difference[42]. The left-hand side and right-hand side are showing the schematic of the indirect conversion type and the direct conversion type, respectively. The following part is described about the FPD, but the radiation imaging using the line sensor is basically the same.

< Indirect conversion type >

In case of the indirect conversion type, radiation enters the scintillator layer. The typical scintillator materials used for the DDA are CsI:Tl and Gd_2O_2S (GOS). When the radiation is absorbed in scintillator, the scintillation light is generated and reaches the photodiode array under the scintillator layer. Then the electric signal is generated by the photodiode. As the radiation is converted to the electric signal via scintillation light, this is called indirect conversion type. As the generated light spreads towards every direction, the light reaches the photodiode pixels not only right below the radiation incidence but also the vicinity of the incidence, so the image taken by the indirect type is blurred by this spreading of the light. The indirect conversion type has the drawback of the spatial resolution in principle. When the energy of the radiation is high, thicker scintillator layer is required to absorb the radiation well, however, it makes the scintillation light spread more, resulting in the lower spatial resolution. Therefore, the compromise between the spatial resolution and the sensitivity is necessary. This brings another drawback. As the relatively thinner scintillator layer needs to be used to keep the spatial resolution high, radiation cannot be fully absorbed in the scintillator layer and reaches the photodiode layer. This cause the radiation damage to the photodiode and the indirect conversion type suffers the deterioration of the performance with operating time.

< Direct conversion type >

On the other hand, semiconductor radiation detectors such as Silicon (Si), amorphous Selenium (a-Se) , CdTe and CZT are classified into the direct conversion type detectors. Recently, gallium arsenide (GaAs) detector is also being developed. The common electrode is formed on the irradiation face of the semiconductor and the bias voltage is applied. The pixel electrode is formed on the opposite side of the semiconductor. The photon of the radiation is absorbed in the semiconductor and the electric charges are generated. They are drifted to the pixel electrodes by the internal electric field and amplified by the connecting readout IC and the radiation image is obtained. As the radiation is directly converted to the electric charge, this type is called Direct conversion type.

The electric charge can reach the pixel electrode right below the absorbed position without spreading, so the sharp image can be obtained. An appropriate semiconductor thickness can be selected by the energy of photon without the risk of blurring the image.

The spatial resolution of the direct conversion detector (CdTe FPD) is compared to that of the indirect detector (CsI:Tl FPD) in Fig.10 and Fig.11 (47)

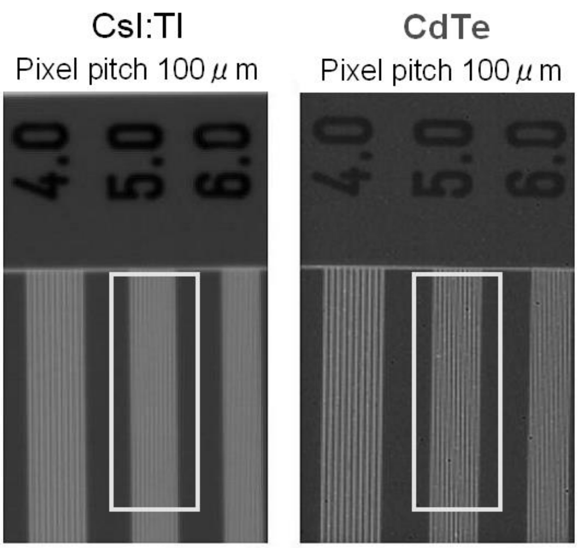

Fig.10 Comparison of X-ray images of a resolution chart pattern taken by the CsI:Tl FPD and the CdTe FPD (47)

Fig.10 shows the images of the resolution chart pattern taken by the CsI:Tl FPD (indirect conversion type) and the CdTe FPD (direct conversion type). Both FPDs have the same pixel pitch of 0.1mm. It is difficult to discriminate the lines of 5 lp/mm by the CsI:Tl FPD (in-direct conversion type). On the other hand, it is clearly possible by the CdTe FPD (direct conversion type). As the pixel pitch of 0.1mm corresponds to 5 lp/mm, this suggests the scintillation light spreads in scintillator layer of the indirect conversion type.

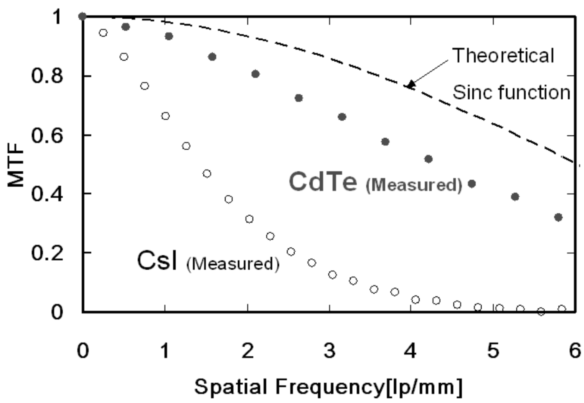

Fig.11 pre-sampling Modulation Transfer Function of CsI FPD and CdTe FPD(47)

Fig.11 shows the pre-sampling Modulation Transfer Function (MTF) taken by the same detector in Fig.10. The MTF value closer to 1 means the sharper image of the edge and the MTF closer to 0 means vague image of the edge. At larger spatial frequency (fine pitch of line pairs), MTF of CdTe FPD is much larger than that of CsI:Tl FPD, clearly showing that the spatial resolution of the CdTe FPD is better than CsI:Tl FPD.

< Photon counting detector >

Photon counting detector is a kind of the direct conversion type DDA. The example of the circuit diagram is shown in Fig.12, which shows the circuit for only one pixel. The photon is absorbed in CdTe and electric charge is generated in proportion to the photon energy. The electric charge is then amplified and the output signal is sent to the pulse height discriminator, where the output signal is compared with the energy threshold value. If the output signal is larger than the energy threshold value, the photon is counted at the counter. In this way, the number of the photon in a certain energy range (bin) is obtained. In case of Fig.12, 4 images for 4 different energy ranges can be obtained. These threshold energies are easily changed by the input from computer.

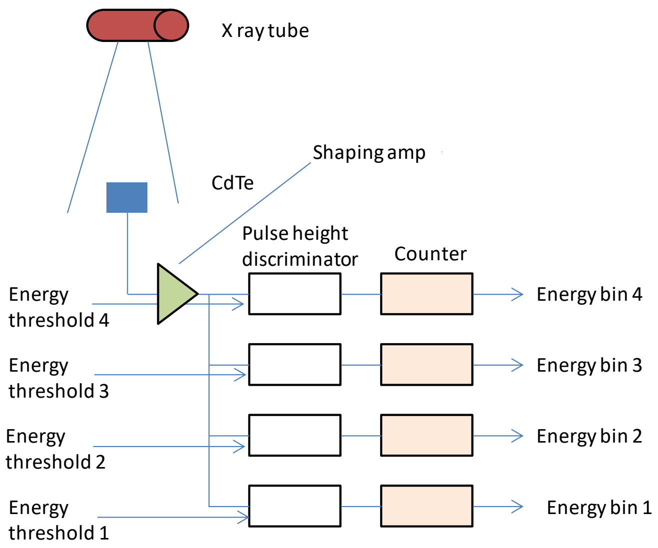

Fig.12 The circuit for the energy discrimination for one pixel

Photon-counting type has the ability of multi energy imaging, which adds the new function of the material discrimination[24,32-37]. This new function is expected to have the big advantage for the medical applications, non-destructive testing, food inspection and security area. CdTe and CZT photon counting detector has been developed for this function.

As described above, the indirect detector using the scintillator cannot be a substitute for CdTe or CZT semiconductor radiation detector in terms of the spatial resolution and multi energy imaging. Direct conversion type using the semiconductor detector will be the possible substitute for CdTe or CZT in principle. Therefore, in the next part, several semiconductor detectors are discussed if they could be the substitute.

<Semiconductor radiation detectors>

Silicon (Si), amorphous Selenium (a-Se)[48-49], Germanium (Ge), Cadmium telluride (CdTe), Cadmium zinc telluride (CZT), Gallium arsenide (GaAs)[50], Mercury iodide (HgI_2) and Thallium bromide (TlBr)[51-53] have been known as the direct conversion semiconductor radiation detectors. Si, a-Se, Ge, CdTe and CZT have been used for applications in the market, but GaAs, HgI_2 and TlBr are still in development phase.

Table1 shows the physical parameters and the typical performance of the semiconductor detectors.

Table 1 Physical parameters and Performance of Semiconductor Radiation Detectors

related pefromance		Si	a-Se	Ge	GaAs	CdTe	CZT	HgI_2	TlBr
Sensitivity	Density (g/cm^3)	2.33	4.39	5.32	5.32	5.85	5.8	6.36	7.56
	Atomic number	14	34	32	31, 33	48, 52	48,30,52	80, 53	81, 35
	Absorption (%) of 100keV X-ray by 1mm thick detector	4%	24%	26%	26%	62%		89%	95%
Energy Resolution	Electron mobility lifetime product (cm^2/V)	0.42 77K	$3x10^{-6}$	0.72 77K	10^{-4}	$2\sim3x10^{-3}$	$10^{-3}\sim10^{-2}$	$1x10^{-4}$	$3x10^{-3}$
	Hole mobility lifetime product (cm^2/V)	0.22 77K	$6x10^{-5}$	0.84 77K	$4x10^{-5}$	$3\sim5x10^{-4}$	$\sim10^{-5}$	$4x10^{-5}$	$\sim10^{-4}$
	Energy Resolution at 122keV (keV)	0.55 77K	-	0.4 77K	-	3.5	4.4	3.2	6.1
	Energy Resolution at 662keV (keV)	0.9 77K	-	0.9 77K	-	7.5	11.8	5.96	11.2
Room Temperature Operation	Band gap (eV)	1.11	2.3	0.665	1.43	1.44	1.44～1.6	2.13	2.68
	Resistivity (Ωcm) at 300K	$2.3x10^5$	$1x10^{12}$	47	$1x10^9$	$1x10^9$	$1x10^{10\sim11}$	$1x10^{13}$	$1.5x10^{10}$
Toxicity[55]	LD50 (mg/kg)	3,160	6,700	—	>15,000	>15,000		18	35[56] LDLo
	Toxicity(oral) GHS category	Not a dangerous sunstance	3	Not a dangerous sunstance	—	4		2	2

- (1) Sensitivity

As already described in section 4 (C), if the X- or gamma-ray is not absorbed in the semiconductor, the radiation cannot be detected at all. Therefore, the absorption ability is primarily important for the high sensitivity.

The energy range more than 20keV is well used in applications such as medical devices and non-destructive testing, food inspection and security system. Fig.13 shows the absorption of the 100keV, 50keV and 20keV X-ray by the detector thickness. They are calculated using the mass absorption coefficient data by National Institute of Standards and Technology[54].

In case of 100keV X-ray, even 10mm thick Si can absorb only 35% of X-ray. The absorption of the a-Se, Ge and GaAs are almost the same, but still 8mm is necessary to absorb 90%. On the other hand, only 2.4mm thick CdTe can absorb 90%. HgI_2 and TlBr can absorb more efficiently and the 1mm thick detector can absorb 90%. The semiconductor with high density and high atomic number show the high absorption efficiency as shown in Table1.

In case of 50keV, the absorption of Si is still low and 10mm thick Si can absorb only 64%. The absorption of 1.4mm thick a-Se, Ge and GaAs reach 90% and 1mm thick CdTe, HgI_2 and TlBr can absorb almost 100%.

In case of 20keV, this energy seems the upper limit for the Si detector, although 1mm thick Si detector can absorb only 64% of X-ray. 1 mm thick of the other semiconductors can absorb almost 100% of 20keV X-ray.

As the generated carriers (electron and hole) have to drift along the thickness direction and reach the electrode, thicker detector increases the possibility of the carrier trap. Furthermore, the bias voltage needs to be increased with the thickness to keep the high internal electric field. However, the bias voltage may exceed the practical range. Thicker the detector, more detector material is required and the detector cost increased. These are the drawbacks of the thick detector and a few mm may be the practical thickness as the imaging detector.

In short, the sensitivity of the Si is too low for the energy range more than 20keV application. a-Se, Ge and GaAs can be used below 50keV, CdTe, HgI_2 and TlBr have the sufficient sensitivity even at 100keV. Therefore, CdTe, CZT, HgI_2 and TlBr are good candidates for the applications listed in 4.(A).1 from the sensitivity point of view.

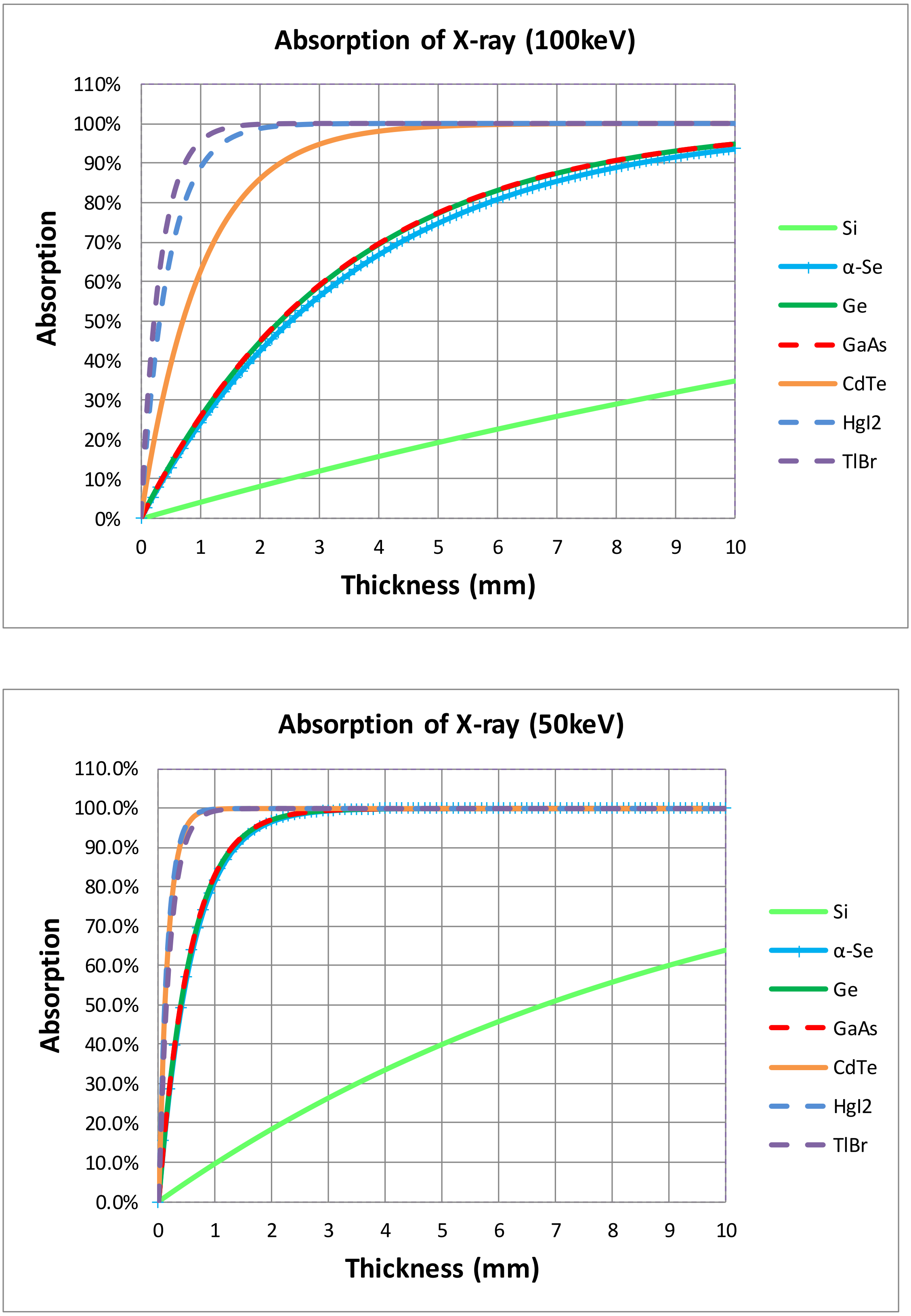

Fig.13 The semiconductor detectors' absorption ratio of the 100keV and 50keV X-ray

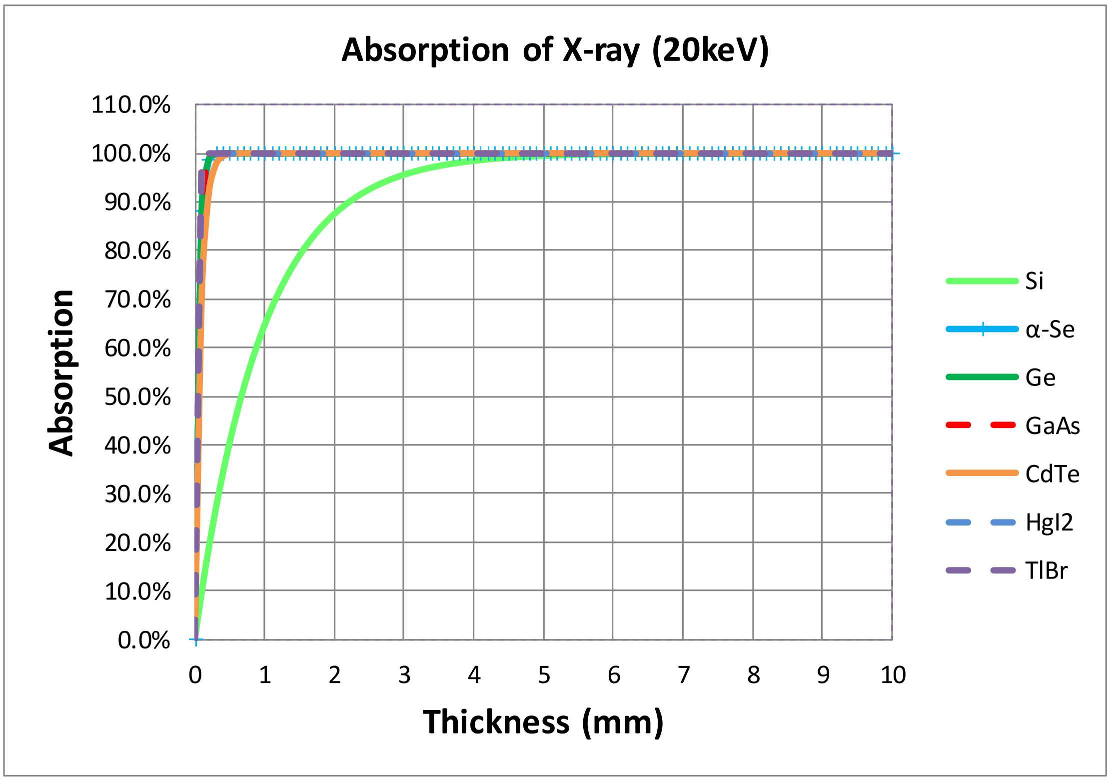

Fig.13 (Cont.) The semiconductor detectors' absorption ratio of the 20keV X-ray

-(2) Energy Resolution

The energy resolution of the detector is determined by the mobility–lifetime products (μτ products). The typical μτ products value and energy resolution of the 122keV (^{57}Co) and 662keV (^{137}Cs) gamma-ray peak are listed in Table1.

CdTe, CZT and TlBr have relatively large μτ products and their energy resolution at room temperature are excellent. a-Se is used for the FPD but the μτ product is very small and cannot resolve the radiation energy. Ge detector shows superior energy resolution when cooled down by liquid nitrogen. That is why it has been used for mainly analysis applications which require very accurate energy information.

-(3) Room temperature operation

As seen in Table1, the band gap of Ge is 0.665eV and the resistivity of the crystal is only 47Ωcm at room temperature, so the leak current is too large for the radiation detector. Therefore, it needs to be cooled at liquid nitrogen temperature (77K). The other semiconductor detectors can be used in room temperature due to the larger bandgap and high resistivity.

Taking the above 3 important requirements and environmental view into consideration, each semiconductor detector is assessed as follows;

-Si

Si is the very good detector at low energy radiation range, for example, less than 10keV. However, the sensitivity is too low for the application listed in 4.(A).1, due to the small atomic number and the density.

-a-Se

a-Se FPD[48-49] is currently used for medical devices, especially mammography because it images only the soft tissue and the X-ray energy is typically less than 35keV. But the sensitivity is not sufficient for the higher energy X-ray applications. Furthermore, a-Se FPD cannot obtain the energy information due to the small μτ products. Therefore, it cannot be used for the applications which need the energy information.

-Ge

Ge has very high energy resolution at liquid nitrogen temperature, but it cannot be used at room temperature due to the small band gap. Because of the requirement of liquid nitrogen cooling, it cannot be used widely in many applications except for the analysis applications in laboratories.

-GaAs

GaAs is a newly developed semiconductor radiation detector[50]. It is still being developed. The sensitivity of GaAs is almost the same as Ge and a-Se, so the application area will be limited like a-Se FPD. As the μτ product is small so far, application using the energy information looks difficult.

-CdTe and CZT

The sensitivity is much higher than a-Se, Ge and GaAs at the energy range more than 20keV, and they are already used in many applications. They can operate at room temperature and cooling system is not necessary for the application device. They also have the sufficient μτ product and the energy resolution is good. Therefore, they are also suitable for the application using the energy information. Utilizing the energy information, the device with material discrimination functions have been developed and are being developed.

-HgI_2

HgI_2 has the very high sensitivity due to the high atomic number and density. It can operate at room temperature. However, it has environmental issue. Mercury is already restricted substance in RoHS. Furthermore, it should be considered that the use of mercury is more strictly restricted by Minamata Convention world-wide. Therefore, it is unreasonable to conceive that HgI_2 could be the alternative of CdTe and CZT.

-TlBr

TlBr(51-53) is composed of high atomic number element (Tl:81, Br:35) and its density is very large (7.56g/cm^3), therefore the absorption efficiency is very high at high energy. However, due to the Tl^+ and Br^- ion migration under the high bias voltage, Tl^+ and Br^- ion accumulate under the electrodes and cause the premature failure of the detector. Some countermeasures have been considered, but still they are not enough for practical applications and further development is required. Moreover, DDA using the TlBr is not available in the market so far. Also, thallium (Tl) is a well-known chemical as a rat poison. The LDLo (Lowest Lethal Dose) of TlBr is only 35mg/kg(56) and the toxicity is very high as well as the HgI_2. Although Tl is not a restricted substance in RoHS, it should not be the alternative of the CdTe or CZT due to the very high toxicity.

The discussion above is summarized in Table 2. Only CdTe and CZT can satisfy all 4 important requirements for the applications listed in section 4.(A).1. There are apparently no alternative materials of CdTe and CZT.

Table 2 : Summary of the comparison of the radiation detectors

	Direct Conversion Type							Indirect Conversion Type
	Si	a-Se	Ge	GaAs	CdTe, CZT	HgI_2	TlBr	
Sensitivity	X	X	X	X	○	○	○	
Spatial Resolution	○	○		○	○			X
Energy resolution	○	×	○ 77K		○	○	○	
Room temperature operation	○	○	X	○	○	○	○	
Toxicity						X	X	
Note			Cooling System required			Minamata convention	Very toxic material	

If this exemption should be expired, in medical field the diagnosis becomes poor and the radiation exposure risk to the patient and the medical staff increase. This is not only in the medical field, but in other fields, such as non-destructive testing, food inspection, baggage inspection and so on. For the society the accuracy of the inspection is absolutely necessary, and the risk of the radiation exposure should be decreased at the same time.

This technology of making image inside the human body or the objects can contribute to the society widely, so imposing the limitation on this technology is not reasonable.

Even if this exemption is expired, the contribution of reducing the amount of cadmium is small and the adverse effects on the society will cause instead.

Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

There are no superior substitutes for CdTe or CZT detectors.

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7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

As the spatial resolution of the indirect conversion DDA using the scintillator is inferior to the direct conversion type using the semiconductor detector in principle, if the substitutes of CdTe or CZT existed, they would be also the direct conversion type. They must have the high sensitivity, the high spatial resolution, the high energy resolution at room temperature operation like CdTe or CZT.

Considering the most recent research on new radiation detectors, we conclude that there is no alternatives for CdTe/CZT detector at present.

Generally speaking, the development of the new semiconductor detector materials takes very long time, the current semiconductor detectors have needed a few decades from the first report to the real application phase. In case of CdTe detector, its performance as the radiation detector was reported in 1967 at first. It started to be used for only a few applications in 2000s. It was finally recognized as the important high-performance detector around 2010. Therefore, it took about 40 years from the initial report to the real applications.

In case of GaAs and HgI_2, their first report as the radiation detector was published in 1963 and 1970, respectively, and they are still in development phase. Considering these situations, in general, new candidate of the detector takes at least 20 years for the development from the initial research to real applications.

As there is no candidate of substitute for CdTe and CZT at present, we believe this situation will not change at least until 2024, which is the current expiry date of the monitoring and control instruments in industry (category 9 industry).

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

Not Applicable

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

- ☐ Authorisation
  - ☐ SVHC
  - ☐ Candidate list
  - ☐ Proposal inclusion Annex XIV
  - ☐ Annex XIV
- ☐ Restriction
  - ☐ Annex XVII
  - ☐ Registry of intentions
- ☒ Registration

  CdTe is registered as the feed material of solar cell

  EC Number 215-149-9

  CAS Number 1306-25-8

2) Provide REACH-relevant information received through the supply chain.
Name of document: _____

Japan Business Council in Europe

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

   ☐ Yes. Consequences? _____

   ☒ No. Justification: The performance becomes deteriorated

2. Can the substance named under 4.(A)1 be substituted?

   ☐ Yes.

   ☐ Design changes:

   ☐ Other materials:

   ☐ Other substance:

   ☒ No.

   Justification: The performance becomes deteriorated by substitution

3. Give details on the reliability of substitutes (technical data + information):

   There are no substitutes which can fulfil the 4 important requirements, that is (1) sensitivity, (2) spatial resolution, (3) energy resolution and (4) room temperature operation.

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

   1) Environmental impacts: N/A
   2) Health impacts: There are negative impacts on the health of patient and the medical staff
   3) Consumer safety impacts: There are negative impacts on the social security

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: N/A

b) Have you encountered problems with the availability? Describe: N/A

c) Do you consider the price of the substitute to be a problem for the availability?

   ☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability? N/A

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☐ Increase in direct production costs

☐ Increase in fixed costs

☐ Increase in overhead

☒ Possible social impacts within the EU

There are negative impacts on the EU citizen’s healthcare, business competitiveness and also the social security.

☐ Possible social impacts external to the EU

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

---

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

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