

JBCE answer to Questionnaire 1 (Clarification)

Exemption 1 of RoHS Annex IV

1st, September 2020

As an applicant, JBCE would like to answer the questions dated on 20th August.

Please kindly find our answers in the attached.

If you have any further questions, please do not hesitate to contact to us.

We are looking forward to continued contribution during the consultation phase of evaluation.

Yours sincerely,

Contact details

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ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 85 multinational companies of Japanese parentage active in Europe.

Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products.

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RoHS exemption IV-1
Answer to the questionnaire 1
from JBCE

(Public Version)

Q1. You mention that a device with cooling system would become too large.

- a. Can you give a qualitative example please? How big should be the cooling system?
- b. Are such devices with an additional cooling system already on the market?

A . 1a

High sensitivity, high spatial resolution, high energy resolution and room temperature operation are very important technical requirements for the radiation detector, as described in Table 2 in our exemption renewal request. Although Ge detector has less sensitivity than CdTe or CZT detector, it is one of the good detector materials with the extremely high energy resolution except it needs to be cooled down to temperature of liquid nitrogen. Therefore, we investigated the cooling system for the Ge detector.

Figures 1a and 1b show examples of these typical Ge detectors, which require a cryostat for liquid nitrogen cooling.

Here, we evaluate the volume of Ge detector element and the volume of the cryostat to cool the detector, for the two typical cases.

Fig. 1a Typical Ge detector

Detector volume: $100\text{cm}^3 = 0.1\text{L}$

Cryostat capacity: 30L

(Occupied space volume: approx. $22.3 \times 22.3 \times 3.14 \times 61 \text{ cm}^3 = 95 \text{ L}$)

Roughly 1000 times of the exact detector volume (0.1 L) is required for cooling.

Ge detector housing

Cryostat

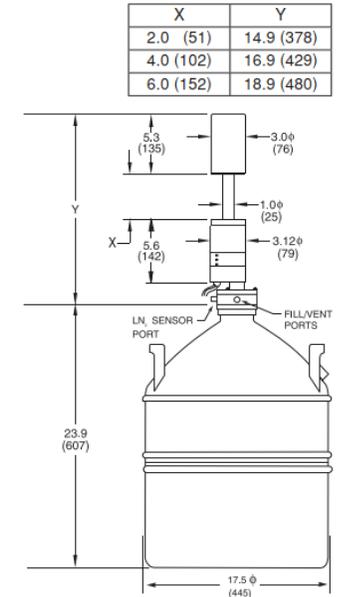


Fig. 1a

Fig. 1b Ge spectrometer for elemental analysis

Detector volume: $1\text{cm}^3 = 0.001\text{L}$

Cryostat capacity 7.5L

(Occupied space volume: approx. $11.5 \times 11.5 \times 3.14 \times 58 \text{ cm}^3 = 24\text{L}$)

A volume of 24,000 times the detector volume (1 cm^3) is required for cooling.

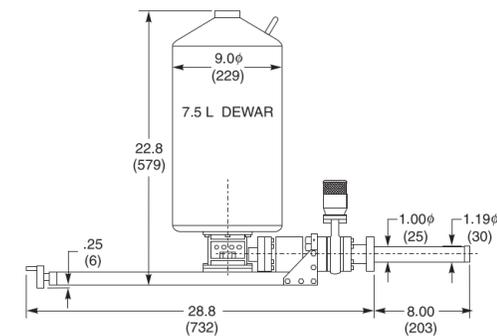


Fig. 1b

The above two examples show that a volume of about 1,000 – 30,000 times the actual detector volume is required for these system cooling.

A 1b.

To the best of our knowledge, there are no general medical radiation imaging systems, no non-destructive testing systems nor no food inspection systems on the market that require cooling with liquid nitrogen.

However the liquid nitrogen-cooled Ge detectors are utilized for very limited measurement fields where very high energy resolution is required, such as radioactivity inspection and elemental analysis.

Fig. 2 shows a Lang counter for lung exposure testing. And most of the device volume is occupied by the cooling system. If this cooling system is not required, the device can be made extremely small. In this case, the measurements are made with a static detector, but a CT system is much more complicated. It is easily imagined that adding such a cooling system to a large, fast-rotating 2D detector would be not realistic.



Fig. 2 Lung counter
(From the Canberra homepage)

Fig. 3 shows an example of a gamma probe used for sentinel lymph node biopsy. The probe is held like a pencil by the doctor during surgery and is used to find sentinel lymph node by detecting gamma radiation from the isotope locating in it. The probe must be lightweight and freely movable, it cannot be cooled with liquid nitrogen.



Fig. 3 Gamma Probe
(Dilon Technology home page)

Q2. You emphasize the need to decrease the exposure time and doses for patients as well as for operators.

a. Can you give an estimation of the exposure time reduction by using Cd-based materials, as well as for the dose reduction for comparable examinations?

b. How is the reduced exposure time relevant for other than medical X-ray devices? Can't it be assumed that the exposure time for samples others than organic tissues is not relevant, and that the exposure for the operators is not higher since different from medical applications the sample can be isolated completely during the X-raying?

A1a.

There is the relation between dose and exposure time as follows

$$\text{dose} = \text{dose rate} \times \text{exposure time}$$

Therefore, “reducing the exposure time” leads to “reducing the dose”.

We picked up three examples of dose reduction / exposure time reduction from the published paper and non published data.

These results shows CdTe detector can reduce the dose / exposure time by about 30~70% when obtaining the same image quality which is taken by the conventional detectors.

Please see following pages for three cases.

1 . Dose reduction comparing a CdTe photon counting CT to a conventional CT with GOS scintillator

S Kappler et al, “A Hybrid Research Prototype CT Scanner with Photon Counting Detector”, IEEE Transaction on Medical Imaging: Special Issue on Spectral CT

A hybrid prototype CT scanner was developed to explore the benefits provided by photon counting CdTe detector. The scanner is equipped with two measurement systems at angle of 95 degree, one is a CdTe counting detector and another is a conventional GOS-based energy integrating detector. Therefore, the direct comparison was possible between the photon counting CdTe detector and the conventional type.

For CdTe detector, energy thresholds at 25keV and 55keV were used to obtain low energy image I_{low} and high energy image I_{high} , respectively. Then the mixed image was created by adding the I_{low} and I_{high} with using the weight of low energy image w . And the weight w is optimized for maximum relative CNR^2 .

$$I_{mix} = w \cdot I_{low} + (1-w) \cdot I_{high}$$

Relative CNR^2 : squared contrast to noise ratio, showing the image quality relative to the conventional system.



Fig.4 Hybrid CT scanner equipped with both CdTe counting detector and conventional GOS-based energy integrating detector.

Fig.5 shows the optimized relative CNR^2 at various X-ray tube voltage. The image quality of the CdTe photon counting system increases with tube voltage. The quality at tube voltage 140kV shows 46% better than the conventional detector at the same patient dose.

Fig.6 shows Relative patient dose needed with CdTe photon counting detector to maintain the iodine CNR^2 delivered by the conventional energy integrating system. The dose with CdTe photon counting detector can be reduced by 32% for the same image quality that obtained by the conventional detector at tube voltage 140kV.

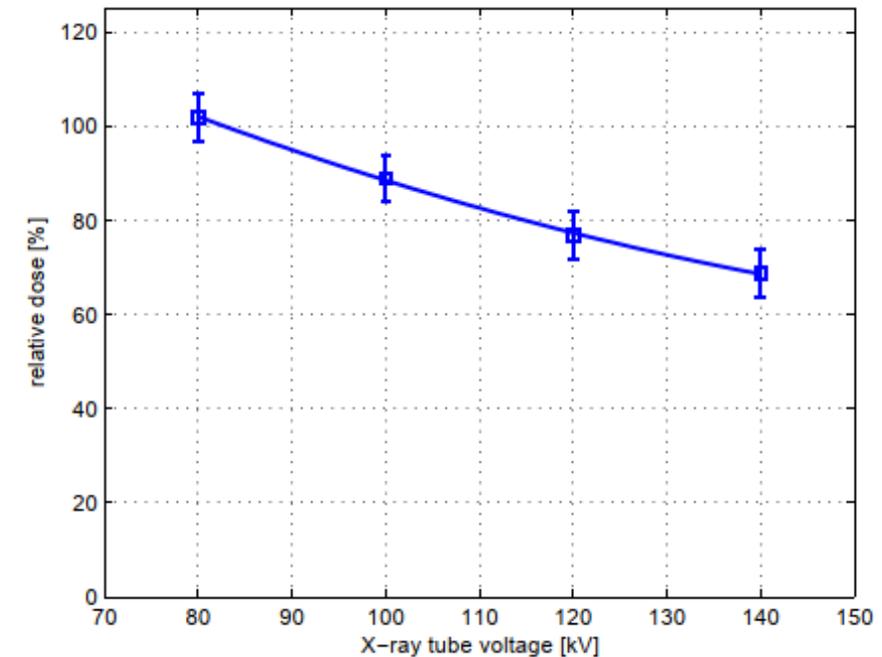
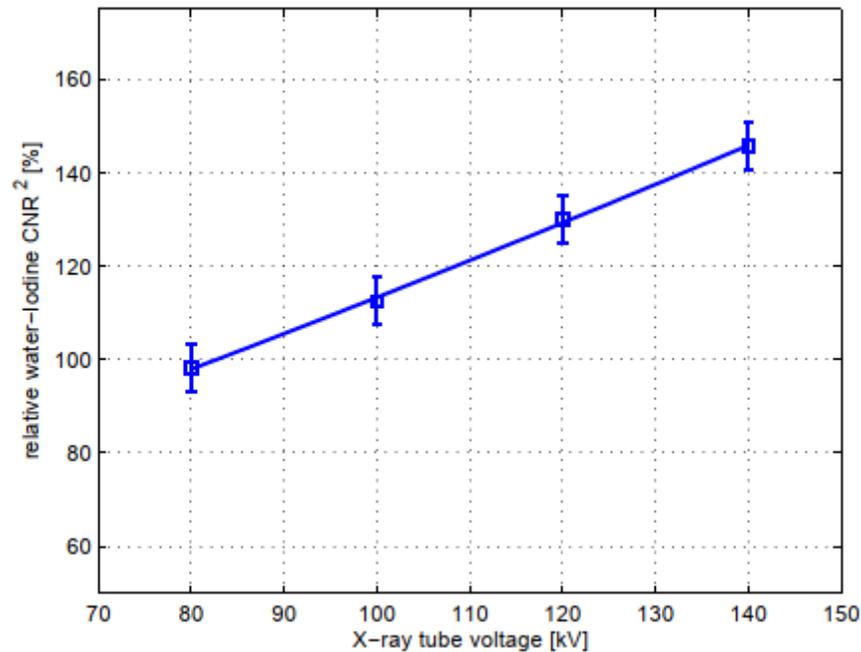


Fig.5 The optimized relative CNR^2 at various X-ray tube voltage

Fig.6 Relative patient dose needed with CdTe photon counting detector to maintain the iodine CNR^2 delivered by the conventional energy integrating system

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the Confidential Information***

III. Comparison of sensitivity between a CdTe gamma camera and a conventional NaI scintillation camera

T Oda, et al. "Evaluation of Small Semiconductor Gamma Camera" Kakuigaku (Nuclear Medicine) 6:pp1-12,2009

The S-shaped phantom images were taken by CdTe gamma camera and a conventional NaI scintillation camera. The exposure time is 2 sec. The image was compared each other visually.

CdTe gamma camera ; Acrorad MGC-1000

NaI scintillation camera ; Shimadzu SNC5100-R

Phantom ; polyethylene tube with inner diameter of 1mm, ^{99m}Tc 30MBq,

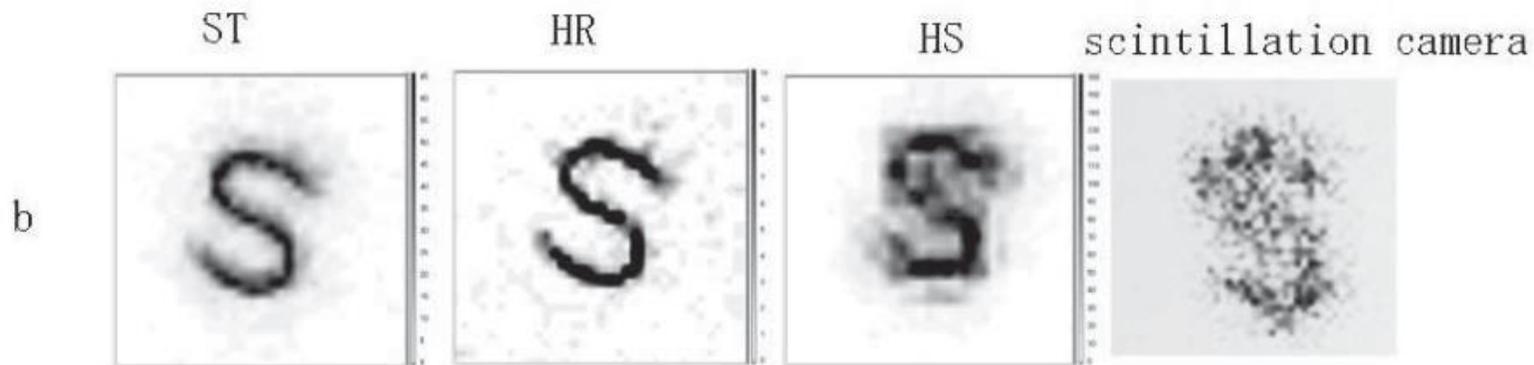


Fig.11 The three on the left were taken with the CdTe gamma camera (ST: standard collimator, HR: high-resolution collimator, HS: high-sensitivity collimator), and the one on the right was taken with conventional NaI scintillation camera

The CdTe gamma camera can identify the S-shaped phantom in 2 seconds, whereas the conventional NaI scintillation camera images have fewer counts and are dispersed, making it difficult to recognize the S-shaped phantom.

From this, it can be seen that the sensitivity of the CdTe gamma camera is much higher than that of the conventional NaI scintillation camera. We estimate that the imaging time of the CdTe gamma camera can be reduced to be roughly half of the conventional scintillation camera. we estimated it from the point assemblage of the image.

In this gamma camera case, it is possible to reduce the exposure time or the dose by about 50%.

A. 2b

In non-medical application areas, radiation detectors have been utilized in various application areas and the operation form is quite different. In case of security inspection, food inspection and so on, it is certain that the risk of the exposure to the operator is not bigger than the case of medical devices, as the sample is isolated from the operator completely. However, plant piping inspections, for example, are inspections that must be performed outdoors, and the situation is very different from the aforementioned. Since the fixed plant is inspected, it is difficult to completely shield the radiation and the risk of exposure for the inspection operator or environment remains. Therefore, it makes sense to reduce the possibility of operator exposure by minimizing the dose and exposure time as much as possible.

For non-destructive testing and security inspections and so on, the reduction in exposure time is also important in another way. In these cases, reducing the inspection time per unit is particularly important. You don't have to wait in a queue for a long time for airport security check. If the inspection time is reduced by half, the number of inspection lines can be halved, which reduces the capital investment. Also, if we can reduce the inspection time or the dose per unit, the frequency of replacing the expensive X-ray tubes can be reduced, the detector damage induced by radiation also can be mitigated, and the operation cost can save accordingly. If we can use the high sensitivity detector with high signal noise ratio in the food inspection, the false alarm rate can be decreased and the excess food waste by mistaking the normal sample for the abnormal one.

As described above, using the high sensitivity detector such as CdTe or CZT can contribute to the society not only by reducing the exposure time but also by various ways

Q3. You mention in page 11 that two isotope nuclides can be used simultaneously to remove the scattered ray. Is it an alternative method to have a clearer image without using CdTe or CZT detector? If yes, does it enable to reduce the exposure time?

A. 3

No, the question is not what we describe in the exemption renewal request.

The clearer image can be obtained by removing the scattered ray which is out of the energy window. On the other hand, using the two radio isotope nuclides simultaneously is a different topic from obtaining clearer image by removing scattered ray. If we can use the detector of high energy resolution like CdTe or CZT, we can set two energy windows for two radioisotope nuclides. In such case, we can dose two radio isotope nuclides to a patient simultaneously and do imaging only once, even when the nuclear medicine diagnostic needs two different isotopes. Without such a detector of high energy resolution, we need imaging twice. In that sense, CdTe or CZT detector can reduce the imaging time considerably when the diagnostics needs two isotope nuclides. The detector with high energy resolution such as CdTe and CZT will be expected to contribute to the new technical innovation of nuclear medicine in near future.

Figure on the bottom shows how the energy spectrum is with the detectors of the different energy resolution. Energy spectrum from ^{123}I and $^{99\text{m}}\text{Tc}$ are taken using conventional NaI scintillator (left) and CZT detector(right). Peak energy of ^{123}I and $^{99\text{m}}\text{Tc}$ are 159keV and 141keV, respectively. As the energy resolution of NaI detector is not so good, the two peaks overlap each other. On the other hand, CZT detector can distinguish two peaks clearly.

Figure is deleted, due to the Confidential Information

Q4. You do not request an exemption for lead in ionization chambers of X-ray imaging systems. Why? Do your members have an alternative to lead in this application?

A. 4

Our members don't have enough information about the ionization chamber, because it is out of our products scope.