

# An Imaging Process for Early Detection of Colorectal Cancer Using a Radioactive Source – Radiation Protection Considerations

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## INTRODUCTION

The Israeli company Check Cap is developing a new system for diagnostic imaging of the large intestine using Compton backscattering of X-ray and gamma radiation emitted from a radioactive source. The new imaging process should become a part of the periodic screening program for early detection of colorectal cancer in men and women aged 50 years and more. This study presents an estimate of the radiation doses delivered and the ensuing health risks to the patient as a result of the imaging process using two potential sources: <sup>191</sup>Os and <sup>201</sup>Tl.

In the proposed imaging process a device (a capsule developed by Check Cap) is designed to be ingested and travel through the GI tract naturally while the patient continues eating normally. The capsule is carrying a sealed radioactive source that emits gamma and X-rays. The radiation source is surrounded by a tungsten cylindrical collimator limiting the radiation beam to specific times and tissue areas. The capsule moves through the colon when it contracts. When the capsule moves the source is brought in front of the collimator holes and remains there throughout the movement and until the capsule sets on the walls of the colon. At times when the capsule rests the source returns to its shielding and is kept shielded from all directions until the next colon contraction. Figure 1a and 1b presents an illustration of the capsule that includes the source tunnel, the tungsten collimator and 3 holes and the surrounding plastic.

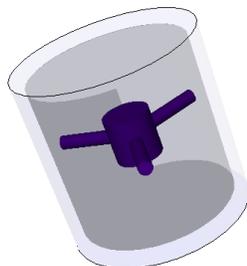


Figure 1a. A side view of the capsule

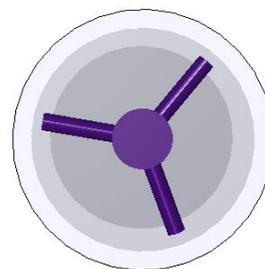


Figure 1b. An upper view of the capsule

When the capsule travels through the GI tract it seeks for polyps, the precursors of colorectal cancer. The collected information is transmitted to a wrist worn data recording device. After the capsule is expelled, the data from the recording unit is downloaded to a computer where dedicated software analyses the information.

The present study estimates the radiation doses and health risks when using two different sources for the imaging process. One source is <sup>201</sup>Tl with an activity of  $3.7 \cdot 10^8$  Bq (10 mCi), for which a statement of opinion was published in 2006<sup>(1)</sup>, and the other is <sup>191</sup>Os with an activity of  $7.4 \cdot 10^8$  Bq (20 mCi). The equivalent dose to the large intestine as well as to other organs in the capsule path and to surrounding organs was estimated for each source and the effective dose was

calculated. The calculations were conducted for both the lower energy photons that are absorbed by the colon wall and the higher energy photons that leak through the collimator wall and reach the body tissues all along the capsule route in the body. In the production process of  $^{191}\text{Os}$  there are contaminating isotopes:  $^{193}\text{Os}$  and  $^{185}\text{Os}$ , their photon energies were also considered in the calculations.

## METHODS

The equivalent dose in the described imaging process depends on many parameters amongst which are: the source activity, the shape of the source, the energy spectrum of the emitted photons, the speed of movement of the source in the colon, the duration of the source route inside the body, the duration of time the source remains unshielded (located in front of the collimator holes), the size and shape of the collimator holes and the source-target configuration.

The radiation dose in the imaging process depends on the photon flux reaching each organ, meaning the cumulative number of photons hitting a unit area on the walls of the organs throughout the process. The value of this flux is determined by the source activity, the speed of movement of the source and the percentage of emitted photons that are used for the imaging process (including the influence of geometric attenuation, the size of the collimator holes and the attenuation of photons by the content of the stomach and intestine). The expected dose is calculated by estimating the average fluence per unit area of the colon wall (and the walls of other organs in the body through which the capsule passes) per unit activity of the source. This fluence is translated to dose using a parameter called the radiation dose per unit fluence, which depends on the photon energy. In the first stage the radiation dose from the photons used for the imaging process is calculated. The dose from the accompanying photons that do not contribute to (and maybe even damage) the imaging process is then calculated.

If the equivalent dose per unit fluence of photons with energy  $E_i$  is  $\gamma_i$  (Sv/photon·cm<sup>-2</sup>), then the equivalent dose  $H_{\text{imT}}$  to organ T from all the photons that reach the colon wall in the imaging process is:

$$(1) \quad H_{\text{imT}} = \sum_i \gamma_i \cdot N_{E_i}$$

Where,  $N_{E_i}$  is the photon fluence in energy  $E_i$  that reach the organ and the summation is for all the photon energies emitted from the source.

$\gamma_i$  values were calculated from the values of exposure rates per unit photon fluence as a function of photon energy from ICRP publication 74<sup>(2)</sup>.

The capsule travels through the GI tract for an average travel time of 72 hours. During its route the capsule can remain in one point for a few minutes or even 10 hours or more. The time spent in each point depends on the patient's individual physiology and the occurrence of colon contractions. The maximal local dose to the colon from the high energy photons escaping the collimator wall was calculated, in order to estimate the occurrence of deterministic effects.

For the  $^{191}\text{Os}$  source, three incidents were addressed and equivalent and effective doses were calculated for each one.

1. The capsule remains nested on the colon wall for the remainder of the patient's life.
2. The duration of transport of the capsule in the colon is extended to two weeks (instead of 72 hours).
3. The sources travels unshielded throughout its route.

## RESULTS

The equivalent doses to the colon and surrounding organs was calculated for each source according to its activity.

Table 1 shows the equivalent doses and the effective dose received when using each of the potential sources ( $^{201}\text{Tl}$  versus  $^{191}\text{Os}$ ).

**Table 1.** The equivalent doses and effective dose received when using a source of  $^{201}\text{Tl}$  ( $3.7 \cdot 10^8$  Bq) and a source of  $^{191}\text{Os}$  ( $7.4 \cdot 10^8$  Bq).

Equivalent doses (mSv)	$^{201}\text{Tl}$ source	$^{191}\text{Os}$ source
Colon	0.1	0.2
Small intestine, Bladder, Uterus, Gonads	$5 \cdot 10^{-3}$	0.01
Stomach	$2 \cdot 10^{-3}$	$4 \cdot 10^{-3}$
Liver, Kidneys, Pancreas, Spleen	$2.5 \cdot 10^{-4}$	$5 \cdot 10^{-4}$
<b>Effective dose (mSv)</b>	<b><math>1.5 \cdot 10^{-2}</math></b>	<b><math>2.6 \cdot 10^{-2}</math></b>

Only 3% (for the  $^{201}\text{Tl}$  source) or 7% (for the  $^{191}\text{Os}$  source) of the effective dose is caused by photons that are essential for the imaging process. The rest of the dose is caused by higher energy photons that leak through the collimator.

The maximal local radiation dose is assessed to be about 7 mGy (for the  $^{201}\text{Tl}$  source) or 11 mGy (for the  $^{191}\text{Os}$  source), under the conservative assumption that the capsule stays for 24 hours close to the same spot on the colon wall between two colon movements. This dose is lower by more than two orders of magnitude than the most relevant dose threshold (3 Gy to large areas of the skin for a 1% incidence of skin erythema). No deterministic effects (tissue reactions) are therefore expected.

The effective dose in each of the above mentioned incidents is described below, for the  $^{191}\text{Os}$  source. When the capsule remains nested on the colon wall the maximal local dose is 90 mGy and the maximal effective dose is 11.8 mSv. If the duration of transport of the capsule in the colon is extended to two weeks (instead of 72 hours) the expected effective dose is 0.092 mSv. When the source travels unshielded (in front of the collimator holes) throughout its route, the expected effective dose is 0.118 mSv.

## DISCUSSION

The effective dose involved in the proposed imaging procedure is of the order of magnitude of the dose caused by a chest X-ray examination. It is much lower than the effective doses in conventional diagnostic radiology (radiography, fluoroscopy, CT) or nuclear medicine imaging processes.

Characteristic values of the effective dose in such procedures are:

Radiography of the pelvis: 0.7 mSv.

CT imaging procedures: 2.3 - 10 mSv.

Nuclear Medicine (SPECT, PET): 1.0 - 6 mSv.

Even in the case of the above mentioned incidents the doses can be compared to doses received by patients in conventional diagnostic radiology. The maximal effective dose received in case of a serious incident where the capsule remains nested on the colon wall for the remainder of the patient's life is of the order of magnitude of the effective dose received in a CT imaging process.

Under conservative assumptions (the LNT theory), the radiation risk associated with the maximal effective dose expected in the imaging procedure under review ( $1.5 \cdot 10^{-2}$  mSv and  $2.6 \cdot 10^{-2}$  mSv for  $^{201}\text{Tl}$  and  $^{191}\text{Os}$ , respectively) is of the order of  $5\text{-}10 \cdot 10^{-7}$ , i.e. 5-10 additional lethal cancer cases among 10,000,000 (10 million) patients aged 50 or more undergoing the screening procedure, when using the  $^{201}\text{Tl}$  or the  $^{191}\text{Os}$  source, respectively<sup>(3),(4)</sup>.

This risk can be compared with the risk associated with well accepted cancer screening procedures such as mammography. According to an assessment by the NCRP<sup>(5)</sup>, the risk of mammography screening is assessed to reach 100 additional death cases from breast cancer as a result of 10 million mammograms performed on women 40-50 years of age.

In conclusion, the radiation risk to the patient in the proposed procedure is very low, in absolute terms as well as relatively to the radiation risk involved in conventional imaging procedures using X-rays (such as fluoroscopy and CT). The risk is also low when compared to the risk involved in established screening procedures such as mammography.

The low risk does not exempt the developers from the justification process required in every instance of medical exposure. As part of the process, one has to compare the radiation risk to the expected clinical benefit. In this comparison one has also to consider alternative imaging techniques that do not cause exposure to radiation, such as colonoscopy, US or MRI.

## REFERENCES

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