

# Guidance on the Recapping of Needles in Radiopharmacy and Nuclear Medicine

## UK Radiopharmacy Group

### 1. EU directive 2010/32/EU and associated UK legislation

EU directive 2010/32/EU on preventing sharps injuries in the hospital and healthcare sector came into force on 11/05/13 and this includes the statement that “re-sheathing of needles is **not** permitted”. The HSE will be introducing UK regulations [regulation 4(1)(c)] based on this directive. Although the directive cannot now be changed, a clarification statement has been issued stating that “the practice of recapping refers to needles without safety and protection mechanisms”. This does allow the HSE some degree of leeway when introducing the regulations.

Following a consultation process on the implementation of this EU directive, the HSE have acknowledged that there are specialist areas where it is appropriate to recap needles as long as certain conditions are met. The specialist areas include radiopharmacy and nuclear medicine and, although it has yet to be confirmed, the HSE are considering redrafting regulation 4(1)(c) to this effect. The conditions that must be met include use of appropriate risk assessments as well as employment of suitable devices that adequately control the risk of injury during the recapping process. Some guidance to help centres meet these conditions is presented in sections 2 and 3 of this document.

### 2. Risk assessments for needle recapping

One reason for having to recap needles in both radiopharmacy and nuclear medicine is so that the contents of a syringe can be measured in a radionuclide calibrator as part of a preparative or clinical procedure. Attempting to measure a syringe with an uncapped needle in a calibrator would be highly likely to result in significant radioactive contamination as well as potentially causing a needle stick injury to the operator. The practice of changing needles prior to measurement would also contain significant risks to the operator: As well as giving the operator a higher radiation dose (particularly to the fingers), there would again be a significant risk of radioactive contamination when the original needle is removed. Removing the needle without recapping would also result in a significant risk of needle-stick injury to the operator.

Another reason for recapping needles in both radiopharmacy and nuclear medicine relates to the shielding of syringes containing radioactive material. Syringe shields made out of lead or similar high-density metals are employed to reduce the radiation exposure to operators handling the syringes. Used syringes must be removed from these shields prior to disposal. This removal is a two-handed process and to reduce the risk of needle stick injury and radioactive contamination it is necessary to first recap the used needle.

Risk assessments must be performed in order to demonstrate that the overall risks associated with not recapping needles is greater than the risk of doing so. Some of the arguments that can be employed in such risk assessments are described in sections 2a and 2b below. They will be slightly different arguments for the practice of radiopharmacy and nuclear medicine. The arguments will also have to be tailored according to local practice. Risk assessments must also demonstrate that the risk to operators performing the recapping is acceptable and as low as reasonably possible. This will necessitate the use of a suitable device such as one that allows single handed recapping (see section 3 for further details on such devices).

#### a. Risk assessments for Radiopharmacy

During radiopharmaceutical production it is often necessary to accurately measure the amount of radioactivity in the contents of a syringe using a radionuclide calibrator. One example of this is when measuring the  $^{99m}\text{Tc}$  activity drawn up from the generator eluate prior to its injection into the ‘cold’ kits. Such measurements are vital in order to ensure that the required activity is achieved within the minimum and maximum activity limits specified by the manufacturer. Failure to perform this measurement could result in radiopharmaceutical products being produced which are outside these limits and this may necessitate a replacement kit having to be manufactured. Producing extra kits in this way would increase staff radiation doses unnecessarily and would thus contravene the ALARA principle in the Ionising Radiations Regulations 1999 [1]. Producing the extra kits may also not be possible due to there being

insufficient  $^{99m}\text{Tc}$  activity in the eluate and this would have a negative impact on the clinical nuclear medicine services being supplied (with delays in patient diagnosis and treatment etc.).

As described in section 2 above, the other reason for recapping needles during radiopharmaceutical production relates to the safe removal of used syringes from syringe guards.

The risks associated with recapping needles in the radiopharmacy relate to needle stick injury, potentially involving the intra-dermal or intra-muscular transfer of a radioactive aseptic product to the operator. The quantity or product transferred would be small and as radiopharmaceuticals only contain tracer amounts of chemically or biologically active ingredients there would be negligible risk of inducing a resulting physiological effect. The risks associated with the radiation will be dependent on the radioisotopes involved and also the radioactive concentration of the radiopharmaceuticals being handled. It can probably be assumed that the maximum transfer volume resulting from a needle-stick injury is of order 5 $\mu\text{l}$  although it is likely to be much less than this [2,3]. At these volumes it is highly unlikely that clinically significant deterministic effects of the radiation (e.g. radiation tissue burn) will be observed. The risk will be greater with isotopes used for NM therapies and this may need to be considered in the risk assessment for individual procedures.

Biological material from patients is handled in a radiopharmacy during procedures to radiolabel blood products. However, the use of needles should generally be avoided when handling blood products during these procedures [4]. This will simplify the risk assessment as the consequence of a needle-stick injury from a biologically contaminated syringe will be far worse than for a needle containing a radioactive but sterile product. In situations where it is necessary to recap needles during a blood labelling process then this will have to be factored in to the risk assessment with clear demonstration that the risk is less than that of not recapping the needles. Further advice on the risks associated with recapping biologically contaminated needles can be found in section 2b.

#### **b. Risk assessments for Nuclear Medicine**

In nuclear medicine practice it is also necessary to accurately measure the amount of radioactivity in the contents of a syringe using

a radionuclide calibrator. For departments drawing up doses from multi-dose vials this involves measuring the syringe with a needle attached or after having removed the needle. Patient doses must be measured prior to injection in order to ensure that the appropriate diagnostic reference level or required therapeutic activity is being administered (within a locally agreed tolerance). A failure to make this measurement would contravene the Ionising Radiation (Medical Exposure) Regulations 2000 [5] and would increase the risk of patients receiving an inappropriate dose. Exceeding the allowed dose limits would unnecessarily increase the radiation risks to the patient and under-dosing would compromise the quality of the NM procedure, potentially resulting in a misdiagnosis.

In nuclear medicine it is also sometimes necessary to accurately measure the amount of radioactivity in the contents of a syringe/needle that has already been used for patient administration. This is the case for all procedures where it is vital to know the exact activity that has been administered and therefore necessary to measure the syringe/needle both before and after injection. An example of this is diagnostic investigations when trying to quantify the uptake of radiopharmaceutical in a particular organ or structure (e.g. thyroid or kidneys). Failure to measure the residual activity would result in a reduced accuracy of the result and this in turn could compromise patient diagnosis and subsequent treatment. Where iv administrations can be given via infusion sets (e.g. butterfly or cannula) it may be possible to avoid having to recap blood-contaminated needles.

As described in section 2 above, the other reason for recapping needles in nuclear medicine relates to the safe removal of used syringes from syringe guards. This removal will often be following i.v administration of a radiopharmaceutical to a patient.

The risks associated with recapping needles prior to patient injection are the same as those described for radiopharmacy in section 2a. The practice of recapping contaminated needles post patient injection results in a significantly higher risk to the operator. This is due to the potential for transmitting blood-borne disease (e.g. hepatitis or HIV) from the patient if a needle stick injury occurs. The ultimate consequence of such an event could be death. Some precautions can be taken to reduce this consequence such as vaccination and staff awareness of their hospital's needle stick

policy. However, the main way of reducing the overall risk is by reducing the likelihood of a needle stick injury occurring. This is achieved through a good system of work and use of a suitable device such as one that allows single handed recapping (see section 3 for further details on such devices).

### **3. Devices to reduce the likelihood of needle stick injury when recapping needles**

As described in section 2, there are situations when the recapping of needles is required in order to minimise the overall risk to staff and patients. Recapping, however, should only be performed using a device that reduces the likelihood of

operators receiving a needle stick injury. Such devices allow recapping to be performed using a one-handed technique. In this way, the unguarded needle is not being moved towards the operators other hand. These devices are available commercially and two examples are shown in figure 1. Prior to purchasing, centres should check that the device fully meets their requirements. This may include checking that it is stable and effective in working conditions and that it is resistant to those products used to clean it (particularly relevant for use in the radiopharmacy). Figure 2 shows how such devices can be used to achieve one-handed needle recapping

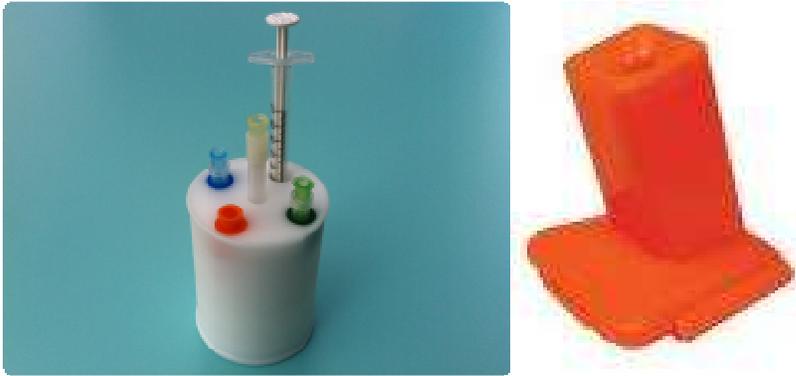


Figure 1 – examples of the needle recapping devices available



Figure 2 – One-handed needle recapping using an appropriate device

## References

1. SI 1999 No.3232 The Ionising Radiations Regulations 1999. London. The Stationery Office. 1999
2. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. J Infect Dis, 1993; 168: 1589-1592
3. Shirazian D, Herzlich BC, Mokhtarian F, Spatoliatore G, Grob D. Needlestick injury: blood, mononuclear cells, and acquired immunodeficiency syndrome. Am J Infect Control, 1992; 20: 133-137
4. [Guidelines for the safe preparation of radiolabelled blood cells](http://www.bnms.org.uk/ukrg/guidance-notes/guidelines-for-the-safe-preparation-of-radiolabelled-blood-cells.html). UK Radiopharmacy Group, <http://www.bnms.org.uk/ukrg/guidance-notes/guidelines-for-the-safe-preparation-of-radiolabelled-blood-cells.html>
5. SI 2000 No.1059 The Ionising Radiation (Medical Exposure) Regulations 2000. London. The Stationery Office. 2000