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Technical Compliance Article

Reference Number: IAC/TCA/IRR99/0001

Title:	**HSE Notification and the Radiation Protection Adviser**
Status:	Open (Issue 1)
Scope:	This TCA provides interpretation and advice regarding the use of Schedule 1 '*Work not required to be notified under Regulation 6*' of the Ionising Radiations Regulations 1999. This article has been written as IonActive Consulting Ltd believes that some users of ionisation radiation sources may be misinterpreting this schedule and not therefore complying with the Regulations.
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Use:	This article is provided for general use by all interested users of ionising radiations sources. It may also be of use to the regulator or Radiation Protection Adviser. IonActive Consulting Ltd accepts no liability for any outcome (including errors or omissions) arising from using the information presented in this TCA. If you are in any doubt about how this TAC might apply to your circumstance contact a suitable Radiation Protection Adviser.
Legislation:	Ionising Radiations Regulations 1999 (SI1999/3232)

1) Introduction

The Ionising Radiations Regulations 1999 (IRR99) places duties on employers and particularly 'radiation employers' (employers that work with ionising radiation). The regulations in their entirety can be found via the IonActive website: http://www.ionactive.co.uk/links_listings.html?c=19.

This particular TCA deals with two important regulations contained in IRR99, they are:

Regulation 6 '*Notification of Specified Work*' which states:

> *This regulation shall apply to work with ionising radiation except -*
>
> (a) work specified in Schedule 1; and
>
> (b) work carried on at a site licensed under section 1 of the Nuclear Installations Act 1965.
>
> *….a radiation employer shall not for the first time carry out work with ionising radiation to which this regulation applies unless at least 28 days before commencing that work or before such shorter time as the Executive may agree he has notified the Executive of his intention to carry out that work and has provided the Executive with the particulars specified in Schedule 2…..*

Some important clauses and sections have been left out for clarity. The essential points contained in this regulation are:

- It does apply unless the work undertaken is specified in Schedule 1.
- If it applies the radiation employer must not start work for the first time using any source of ionising radiation before they have given the HSE notice (providing at the least the details specified in Schedule 2 of IRR99).

Regulation 13 '*Radiation Protection Adviser*' which states:

> *(1) Subject to paragraph (3), every radiation employer shall consult such suitable radiation protection advisers as are necessary for the purpose of advising the radiation employer as to the observance of these Regulations and shall, in any event, consult one or more suitable radiation protection advisers with regard to those matters which are set out in Schedule 5.*
>
> *(2) Where a radiation protection adviser is consulted pursuant to the requirements of paragraph (1) (other than in respect of the observance of that paragraph), the radiation employer shall appoint that radiation protection adviser in writing and shall include in that appointment the scope of the advice which the radiation protection adviser is required to give.*
>
> *(3) Nothing in paragraph (1) shall require a radiation employer to consult a radiation protection adviser where the only work with ionising radiation undertaken by that employer is work specified in Schedule 1.*

Some important clauses and sections have been left out for clarity. The essential points contained in this regulation are:

- It does apply unless the work undertaken is specified in Schedule 1.
- If it applies the radiation employer must at least consult a Radiation Protection Adviser (RPA) and in most cases will need to appoint them in writing.

This article has been written as IonActive Consulting believes that some users of ionising radiation sources are not using Schedule 1 of IRR99 correctly. In some cases this may be due to manufacturers or suppliers of such sources giving incorrect information (or no information at all).

It is important to note that Schedule 1 has nothing to do with the Radioactive Substances Act 1993 (RSA93), Registrations for Open or Closed sources, or Exemption Orders (made under the Act). Therefore, if you are informed that a source you have purchased is covered under the '*Radioactive Materials (Testing Instruments) Exemption Order 1985*' (or other such order) this does not mean that source is exempted from the requirements of Schedule 1 IRR99.

Advice with for compliance with the above Act can be obtained from IonActive Consulting Ltd.

For the rest of this article the following matters are considered:

- Using Schedule 1 (simple cases).

For most users of ionising radiation sources simple correct interpretation is all that is required. For some particular users, the interpretation needs to be made after considering how IRR99 actually applies. For this the following additional matters are considered:

- Application of IRR99 (e.g. practice, radon, any other work).
- Definition of '*radioactive substances*' (for use with Schedule 1).
- The role of the RPA with respect to the Radioactive Substances Act 1993.

2) Using Schedule 1

Before delving into Schedule 1 it is useful to consider the information contained in Schedule 8 '*Quantities and concentrations of radionuclides*'. Parts of Schedule 1 use this data as a means of determining its applicability (and therefore whether specific requirements in Regulations 6 and 13 apply). The following table shows the general form of Schedule 8 with some typical data added which will be used for the case studies in this section.

Table from Schedule 8 (Part 1)

1	*2*	*3*	*4*	*5*
Radionuclide name, symbol, isotope	***Concentration for notification. Regulation 6 and Schedule 1 (Bq/g)***	***Quantity for notification. Regulation 6 and Schedule 1 (Bq)***	***Quantity for notification of occurrences. Regulation 30(1) (Bq)***	***Quantity for notification of occurrences. Regulation 30(3) (Bq)***
Hydrogen				
Tritiated Compounds	$1\ 10^{6}$	$1\ 10^{9}$	$1\ 10^{12}$	$1\ 10^{12}$
Elemental	$1\ 10^{6}$	$1\ 10^{9}$	$1\ 10^{13}$	$1\ 10^{10}$
Phosphorus				
P-32	$1\ 10^{3}$	$1\ 10^{5}$	$1\ 10^{10}$	$1\ 10^{6}$
Cobalt				
Co-57	$1\ 10^{2}$	$1\ 10^{6}$	$1\ 10^{11}$	$1\ 10^{7}$
Nickel				
Ni-63	$1\ 10^{5}$	$1\ 10^{8}$	$1\ 10^{11}$	$1\ 10^{9}$
Samarium				
Sm-147	$1\ 10^{1}$	$1\ 10^{4}$	$1\ 10^{7}$	$1\ 10^{5}$

For the purposes of this TCA the two important columns are 2 and 3 (shaded yellow). The first gives activity quantities in Bq/g, the second gives a total quantity (on the premise at any one time) in Bq.

Unsealed radioactive materials, Schedule 1, paragraphs (a) and (b)

> *1. Work with ionising radiation shall not be required to be notified in accordance with regulation 6 when the only such work being carried out is in one or more of the following categories -*
>
> *(a) where the concentration of activity per unit mass of a radioactive substance does not exceed the concentration specified in column 2 of Part I of Schedule 8;*
>
> *(b) where the quantity of radioactive substance involved does not exceed the quantity specified in column 3 of Part I of Schedule 8;*

Two important criteria in the above paragraphs are that:

- It refers to '*the only such work being carried out*'
- It refers to '*one or more the following categories*'

This therefore implies that any work you undertake which exceeds the quantities stated in *either* (a) *or* (b) or both will require notification (Regulation 6). It is then implicit that Regulation 13(3) does not apply and you are not exempt from the requirements to consult a suitable RPA (formal advice will need an appointment).

Case Study A

A small pharmaceutical company is undertaking some trials using 1 MBq of a tritiated compound. They will undertake 10 trials in a year but will never have more than 10 MBq of the radionuclide on their premises at any one time. They have contacted a local university RPA for informal advice and they have obtained an authorisation from the Environment Agency to accumulate and dispose of radioactive organic liquid waste. There is no other use of ionising radiation on site.

Using the table from Schedule 8 (partly reproduced above) it is unlikely that the values in column 2 are exceeded (a check on specific activity will determine this) and the values in Column 3 are certainly not exceeded. On this basis there is no need to notify the HSE under Regulation 6 or consult or appoint a RPA under Regulation 13. Notwithstanding this, and as indicated in the above case study, there is no reason why you can not consult with a RPA if you wish (you do not necessarily need to appoint then in writing if the only advice required is to determine if formal consultation is required and how the regulations apply).

You are advised to read the information given in section5 of this TCA. Although this case study shows that RPA consultation and appointment under IRR99 is not required, the conditions of the authorisation made under RSA93 may well require you obtain advice from a RPA or '*other suitably qualified person which is agreed with the agency in writing*'.

Case Study B

A university professor wishes to carry out a single experiment using phosphorus 32 (P-32). He estimates that it will require 500 KBq but the minimum order will be 9.25 MBq. He wants to get on with this experiment right way and does not want health and safety considerations to adversely affect his important research. The university does not undertake any other work involving ionising radiation.

The professor will need to slow down and consider this matter carefully with the university authorities' health and safety team. The quantities required exceed column 3 (the limit is 100 KBq). They will need to inform the HSE (Regulation 6) and will need to consult with a RPA (and appoint them in writing since formal consultation is likely). It should be noted that regardless of the need (or otherwise) to provide notification to the HSE or appoint a RPA, the rest of IRR99 needs to be complied with absolutely. Exemption from such notification or appointment does not provide exemption from the rest of IRR99 (or duties under RSA93).

Sealed radioactive materials, Schedule 1, paragraph (c)

c) where apparatus contains radioactive substances in a quantity exceeding the values specified in sub-paragraphs (a) and (b) above provided that -

(i) the apparatus is of a type approved by the Executive;

(ii) the apparatus is constructed in the form of a sealed source;

(iii) the apparatus does not under normal operating conditions cause a dose rate of more than 1μSvh-1 at a distance of 0.1m from any accessible surface; and

(iv) conditions for the disposal of the apparatus have been specified by the appropriate Agency;

This section from Schedule 1 allows for the limits contained in Schedule 8, columns 2 and 3 to be conditionally exceeded. If these values are exceeded but all of the conditions in sub-paragraph (i) to (iv) are complied with, then no HSE notification or RPA appointment is required.

IonActive Consulting believes that this single paragraph has caused many entities to incorrectly decide not to undertake HSE notification or RPA consultation / appointment. The cause of the problem resides in sub-paragraph (i) which requires that '*the apparatus is a type approved by the Executive*'. The assumption appears to be that if the apparatus was 'not approved' then it would not be allowed to be used (or

sold, or supplied etc). Therefore the decision is made that since the apparatus is readily obtainable it must be 'approved'.

There are only three type approvals in existence from the Executive (HSE) and these are:

- **TA1** (Ionisation chamber smoke detectors containing Americium-241 installed in premises or a workplace).
- **TA2** (Self-luminous fire safety signs or other devices in which the only radioactive substance is one or more gaseous tritium light sources).
- **TA3** (Ionisation chamber smoke detectors containing not more than 40 kBq Americium-241 …. where no more than 500 are present on single premises any one time).

Detailed information on these type approvals can be found on our website at: http://www.ionactive.co.uk/regulationlist.html?c=2 (last link on that page).

This significance of sub-paragraph (i) (of Schedule 1, paragraph c) is best determined by considering the following case studies:

Case Study C

A research institute is planning to purchase a gas analyser which incorporates a 185 MBq sealed Ni-63 source. They have already previously notified the HSE under Regulation 6 for work they undertake using P-32. They have an appointed RPA who has advised them that they do not need a registration under RSA93 to hold a closed Ni-63 source, since it will be exempt under the Radioactive Materials (Testing Instruments) Exemption Order 1985.

185 MBq of Ni-63 exceeds the value in column 3 of the Schedule 8 table (see table above). Since paragraphs (a) and (b) can not be applied we then see if the conditions in paragraph (c) can be met which would then avoid then need for HSE notification. (Whilst the institute has already notified the HSE of its work with P-32, inspection of Schedule 2 in IRR99 shows that the use of a sealed source would require notification for the first time irrespective of any notification having been made for the P-32). Whilst sub paragraphs (ii) to (iv) of Schedule 1 paragraph (c) can be met, sub paragraph (i) can not – the Ni-63 device is not apparatus approved by the HSE. Therefore, in this case notification under Regulation 6 is required. Furthermore, if no RPA had been previously appointed, one would need to be consulted and might need to be appointed.

Case Study D

A health and safety manager finds that the premises he looks after has a number of installed safety signs, which on inspection contain radioactive material (tritium gas). On speaking to the Environment Agency he is advised that he needs a closed source registration as the current exemptions under RSA93 do not apply. The premises has no other forms of ionising radiation but the manager is concerned as the activity of the signs appears extreme (>10 GBq).

Inspection of paragraphs (a) and (b) reveal that the column 3 value for elemental H-3 in Schedule 8 is exceeded. However, on close inspection of sub-paragraphs (i) –(iv) of paragraph (c), it appears that all conditions are met. Certainly sub-paragraphs (ii) – (iv) are met, and after comparison with the Type Approval Certificate **TA2** it is decided that sub paragraph (i) is also met – i.e. the safety signs are '*apparatus of a type approved by the HSE*'. Therefore, no notification to the HSE is required under Regulation 6 and there is no need to consult or appoint a RPA under Regulation 13. The following should be noted:

- Sub-paragraph (i) will only apply if it can be shown that the apparatus (e.g. safety signs) meet the conditions of **TA2**.
- In order to establish if the conditions in **TA2** can be met, advice can still be obtained from a RPA if preferred.
- You may still consider consulting and appointing an RPA if, for example, you have a number of these signs which require disposal in compliance with RSA93.

Electrical apparatus, Schedule 1, paragraphs (d) and (e)

(d) the operation of any electrical apparatus to which these Regulations apply other than apparatus referred to in sub-paragraph (e) below provided that -

(i) the apparatus is of a type approved by the Executive; and

(ii) the apparatus does not under normal operating conditions cause a dose rate of more than 1µSvh-1 at a distance of 0.1m from any accessible surface;

(e) the operation of -

(i) any cathode ray tube intended for the display of visual images; or

(ii) any other electrical apparatus operating at a potential difference not exceeding 30kV,

provided that the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1μSvh-1 at a distance of 0.1m from any accessible surface

Paragraphs (d) and (e) deal with electrical apparatus which may produce ionising radiation (i.e. x-rays) by the acceleration of electrons in a vacuum. For paragraph (d) both conditions in sub-paragraph (i) and (ii) need to be met to avoid HSE notification and RPA consultation / appointment. For paragraph (e), either / or sub-paragraphs (i) and (ii) need to be met, subject to the dose rate limits specified not being exceeded, and if so will negate the need for HSE notification and RPA consultation / appointment.

Case Study E

A geological research company has installed a 120KV XRD (x-ray diffraction) unit in their laboratory. The unit is fully contained and automatic. The installer's critical examination report shows that dose rates were < 0.2 μSv/h around the external surfaces of the equipment. No measurements are available for non-routine use where interlocks may need to be defeated for the purposes of beam alignment. The company does not use any other sources of ionising radiation.

Inspection of paragraph (d) firstly shows that paragraph (e), which deals with cathode ray tubes and apparatus operating at <30kV, does not apply. Furthermore, whilst the critical examination report (and instrument specification no doubt) shows that external dose rates meet the conditions of sub-paragraph (ii), the XRD equipment is not '*apparatus of a type approved by the Executive*'. Regulation 6 does apply and the company should notify the HSE before starting to use the equipment for the first time. Regulation 13(3) does not apply and so the company should be consulting a RPA, and may need to appoint them in writing. In this case study the company should have initially consulted with a RPA where they would have established the need to comply with Regulation 6 absolutely.

3) Application of IRR99

Section 2 has presented some relatively simple case studies showing how Schedule 1 applies to typical types of work involving ionising radiation. In most circumstances it is relatively simple to compare activity limits described in paragraphs (a) and (b) of that Schedule with the values in columns 2 and 3 of Schedule 8. There are however some limited cases where an employer may use substances containing naturally occurring radioactive materials, where the activity limits described are exceeded and where the material is unsealed, but still not require to undertake HSE notification or consult a

RPA. In order to investigate this situation it will be useful to consider another case study.

Case Study F

A company is using 1kg a solid samarium material for part of their process. One of the employees reads on the internet that samarium is 'naturally radioactive' and consults the company health and safety adviser. The adviser needs to establish how the company is working with this material and how IRR99 might apply. Some calculation shows that the dominant radionuclide in this material is Sm-147. Furthermore, the total activity of Sm-147 appears to be 140 KBq and the specific activity is therefore 140 Bq/g. The values in columns 2 and 3 of Schedule 8 are therefore exceeded and would indicated that HSE notification is required under Regulation 6 and RPA consultation / appointment under Regulation 13.

Before considering how IRR99 might treat this material the company concerned needs to determine what they are doing with it. Regulation 3 of IRR99 states the following with respect to 'application':

(1) Subject to the provisions of this regulation and to regulation 6(1), these Regulations shall apply to -

(a) any practice;

(b) any work (other than a practice) carried out in an atmosphere containing radon 222 gas at a concentration in air, averaged over any 24 hour period, exceeding 400 Bq m-3 except where the concentration of the short-lived daughters of radon 222 in air averaged over any 8 hour working period does not exceed 6.24 × 10-7Jm-3 and

(c) any work (other than work referred to in sub-paragraphs (a) and (b) above) with any radioactive substance containing naturally occurring radionuclides.

Paragraph (b) of Regulation 3 can be ruled out completely which will leave (a) and (c). In order to consider paragraph (a) and decide if the work constitutes a practice we need to look at a definition of a practice which is given in Regulation 2 and states:

(a) the production, processing, handling, use, holding, storage, transport or disposal of radioactive substances; or

(b) the operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5kV,

> *which can increase the exposure of individuals to radiation from an artificial source, or from a radioactive substance containing naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties;*

Interpretation of this definition reveals the following:

- Samarium is being used and handled
- Exposures are not being increased from the samarium (which contains radionuclides of natural origin) – as defined – since it is not being processed for its radioactive properties.

On that basis we can say that Case Study F does not constitute a practice and must therefore fall within paragraph (c) of Regulation 3 i.e. '*any work (other than work referred to in sub-paragraphs (a) and (b) above) with any radioactive substance containing naturally occurring radionuclides*'.

The significance of this will become clearer in the next section where we look at the definition / interpretation of '*radioactive substances*' for the purposes of IRR99.

4) Radioactive substances – interpretation in IRR99

In Regulation 2 of IRR99 the following is stated for 'radioactive substances':

> *means any substance which contains one or more radionuclides whose activity cannot be disregarded for the purposes of radiation protection;*

The key words in the above interpretation are '*cannot be disregarded for the purposes of radiation protection*'. The implication is that some substances can be disregarded where this will not compromise radiation protection.

The Approved Code of Practice (ACOP) to IRR99 '*L121: Working with ionising radiations*' (ISBN 0 7176 1746 7) states in paragraph 9 that radioactive substances used in a practice can not be disregarded for the purposes of radiation protection where the values in columns 2 and 3 of Schedule 8 are exceeded. In terms of activity Case Study F exceeds the relevant values but it is not a practice.

Paragraph 11 of the ACOP states the following (exactly):

> **In the special case of substances containing naturally occurring radionuclides used in work other than a practice, their activity cannot be disregarded for the purposes of radiation protection where their use is**

likely to lead to employees or other people receiving an effective dose of ionising radiations in excess of 1 millisievert in a year.

What is then required is a risk assessment under Regulation 7 of IRR99 to determine if the samarium as used can lead to an employee of other person receiving an annual radiation dose exceeding 1mSv. This assessment needs to be specific to the type and form of the material. For example, an assessment might show that use of a solid samarium compound will never exceed the 1mSv limit, where as its use as a fine powder might exceed the limit due to internal radiation exposure (via inhalation or ingestion).

If it can be confidently shown that the use of samarium as described in Case Study F will not constitute significant exposure to employees above normal background levels (i.e. substantially less than 1mSv with appropriate factors of safety) then its radioactive nature can be disregarded. If this is the case then there is:

- No requirement to notify the HSE (Regulation 6)
- No recruitment to consult or appoint a RPA (Regulation 13)

Finally, having undertaken a fairly rigorous assessment of IRR99 interpretations to determine that RPA consultation is not require, the safety adviser in Case Study F might well decide to consult with an RPA in order to determine that there is no requirement! Regulation 13 allows for this initial consultation which does not require prior appointment.

5) The RPA and RSA93

All the discussion regarding the need to consult or appoint a RPA has been with direct reference to the requirements of IRR99. The RPA is defined in Regulation 2 of IRR99 and the requirements to consult and appoint are given in Regulation 13.

RSA93 makes no reference to the RPA – there is no direct equivalent. However, Article 47.2 of *European Community Basic Safety Standards Directive 96/29/Euratom* makes reference to Qualified Experts. The UK non-nuclear sector has not adequately defined what a Qualified Expert is, but many have assumed (correctly and incorrectly depending on suitability) that a RPA can be this person.

Whether an RPA can be a Qualified Expert is down to their '*suitability*' – i.e. can they offer advice on compliance with RSA93? The important point to note is that it is IRR99 which requires the appointment of the RPA and not RSA93. Despite this, the term RPA is now being widely used in authorisation certificates (for the accumulation and disposal of radioactive wastes) issued under RSA93 by the Agencies (e.g.

Environment Agency). A typical extract of a modern authorisation certificate will state the following:

> *provision for consultation with such suitable RPAs….for the purpose of advising the user as to compliance with the limitations and conditions of this authorisation…*

The above statement will normally be found in Schedule 1, section 1.a of a typical authorisation. The above statement has been shortened for clarity but will include words to the effect '…*RPAs or other suitable qualified persons which may be agreed with the Agency in writing*….'.

The significance of the above statement is that:

- The RPA will need to be appointed 'to be consulted' but there is no statutory duty to do so under RSA93 (IRR99 does this).
- The RPA needs to be 'suitable'. Under IRR99 it is up to the radiation employer to determine suitability and it makes sense that they take this role under RSA93.

Case Study G

A small pharmaceutical company works with small quantities of H-3 (500 KBq at any one time). The activity is incorporated into samples which undergo liquid scintillation counting. The H-3 waste, consisting of organic liquid in vials, is accumulated and disposed of under an authorisation issued by the Environment Agency. The authorisation requires that the company makes provision to consult with a RPA….

Inspection of columns 2 and 3 of Schedule 1 (IRR99) will show that the activity limits are unlikely to be exceeded and there is therefore no statutory need to notify the HSE under Regulation 6 or consult or appoint a RPA under Regulation 13.

In this situation the company does not need to consult or appoint a RPA. However, whilst their authorisation has no influence on the interpretation of Schedule 1 values, it clearly requires that the company '*make provision for consultation*'. In these circumstances there is no statutory need under IRR99 (or RSA93) to appoint that person in writing - even if formal advice (for compliance with RSA93) is required on a regular basis. That said, sections 1 and 2 in Schedule 1 of a typical authorisation are '*management conditions*', made for compliance with the limitations and conditions. It is very likely that the Agency would require the RPA to be appointed in order to demonstrate that adequate provision for advice has been made. Therefore,

notwithstanding the absence of statutory requirements to appoint (Regulation 13, IRR99), most companies in this situation will appoint the RPA as if this were required by IRR99. In Case Study G it is likely that the RPA appointment letter will detail the optional advice required by IRR99 and that which is required to meet the conditions under RSA93.

If in doubt:

- Consult with a suitable RPA. For relatively simple cases a good provider of RPA services should offer this for free.