Environment Agency

**Environmental Permitting Regulations (England and Wales) 2010**


**Regulatory Guidance Series, No RSR 2**

# The regulation of radioactive substances activities on nuclear licensed sites

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## A QUICK GUIDE

This is high level legal and policy guidance on how we regulate radioactive substances activities on nuclear licensed sites under the Environmental Permitting (England and Wales) Regulations 2010. It will change with changes in Regulations, Government guidance and experience of applying the Regulations.

This document complements our other regulatory guidance to describe in more detail how we regulate radioactive substances activities on nuclear licensed sites, where there are requirements specific to radioactive substances regulation (RSR).

We regulate these sites with the primary purpose of protecting the public from harm from the discharges of radioactive waste. We also seek to protect the wider environment. We regulate within a framework of extensive Government Policy, Strategy and Guidance on the management and disposal of radioactive waste. In summary we require operators to protect people and the environment by minimising the generation of radioactive waste, minimising the amount of radioactive waste that has to be discharged into the environment and discharging that waste in ways that minimise the resulting radiological impact on the public and protect the wider environment. We require operators to assess the dose impact on the public.

The introduction of RSR into environmental permitting has not altered the legal and policy requirements of the regime, nor changed the respective responsibilities of ourselves and the HSE (NII) on nuclear licensed sites. There have been some changes to our permitting practices, including consultation, and in terminology.

This document provides an overview of our policy and regulatory approach to nuclear licensed sites and refers out to other documents for more information.

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**CONTENTS**

# 1. INTRODUCTION

The Environment Agency is responsible under the Environmental Permitting Regulations (EPR) for regulating all disposals of radioactive waste on and from nuclear licensed sites (NLS) in England and Wales**.** "Disposals" of radioactive waste include discharges into the atmosphere, discharges into the sea, rivers, drains or groundwater, disposals to land, and disposals by transfer to another site.

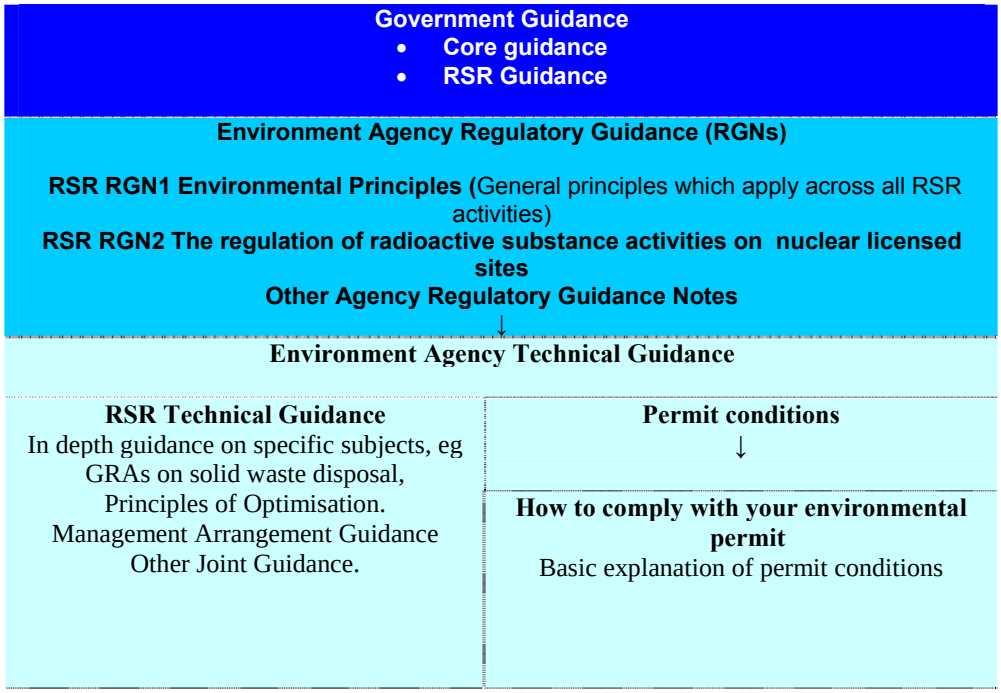
We regulate these sites with the purposes of protecting the public from harm from the discharge and disposal of radioactive waste and to protect the wider environment. We regulate within a framework of extensive Government Policy, Strategy and Guidance on the management and disposal of radioactive waste. These are summarised in the Government Guidance on Radioactive Substances Regulation (RSR) under the EPR. In summary we require operators to protect people and the environment by minimising the generation of radioactive waste, minimising the amount of radioactive waste that has to be discharged into the environment, discharging that waste in ways that minimise the resulting radiological impact on the public and protect the wider environment, and using the optimal route for disposal of solid waste. We require operators of nuclear licensed sites to assess the dose impact on the public

The term 'nuclear licensed sites' (NLS) refers to sites that have a nuclear site licence under the Nuclear Installations Act 1965 or where the period of responsibility of the licensee has not come to an end. We also include sites that have applied for, but not yet been granted, such a licence. Activities for which a nuclear site licence is required include nuclear power generation, nuclear fuel manufacturing and reprocessing, uranium enrichment, operation of research reactors, some national defence activities and some radioactive waste processing and disposal. All of these activities create, to a greater or lesser extent, radioactive wastes that must be managed and disposed of, in some cases over a long period of time.

The Nuclear Installations Act 1965 (NIA65) and associated site licences cover certain regulatory requirements on nuclear licensed sites that we would otherwise regulate as a radioactive substances activity. These differences depend on whether the operator holds a nuclear licence (the licensee) or does not (a "tenant"). The regulator under the NIA65 is HSE (NII) and we co-operate with the NII in exercising our respective functions.

This guidance is part of series of documents which accompany the Environmental Permitting Regulations. The series consists of Government Core Guidance for Environmental Permitting (England and Wales) and on the RSR regime. We have in turn provided policy and technical guidance on the implementation of the environmental permitting regime in general and, through this document, regulatory guidance on RSR-specific matters in relation to the regulation of nuclear sites. The RSR documents fit together as shown in figure 1.

**Figure 1 The structure of RSR Environmental Permitting Guidance**




We have developed Radioactive Substances Regulation Environmental Principles (REPs) to form a consistent and standardised framework for the assessments and judgements that we must make when regulating radioactive substances. We have published these as our guidance document RSR1 in this series. We have developed this principles-based approach to regulation based on the International Atomic Energy Authority (IAEA) approach to safety standards, modified to be more relevant to our regulatory role in relation to the protection of the environment rather than safety. We have also written the principles to be consistent, as far as practicable, with the requirements of the HSE safety assessment principles (SAPs), to

- facilitate a more integrated approach by operators to health, safety and environment issues on nuclear sites, including joint documentation and submissions; and
- ensure common requirements placed on operators by the HSE and us, where appropriate.

The introduction to the REPs describes how we developed them and how, in general terms, we shall apply them in practice. In time we aim to develop further technical guidance to support the consistent application of the principles in practice.

In this document we cover

- the permitting process for nuclear licensed sites;
- the principles of radiological protection and their implementation in practice;
- the implementation of the RSR legal and policy requirements during permitting;
- interactions with other authorities.

This guidance describes the application of environmental permitting to licensees and tenants on nuclear sites so far as is necessary to present a comprehensive picture of the regulatory requirements for such sites. It does not cover the process for staged regulation of a geological disposal facility, and we plan to develop that separate guidance during the next year . Tenants should also refer to RSR3 Non-Nuclear Sites in relation to the “keeping or use” of radioactive materials.

We also provide separately more detailed guidance on matters such as how assessments and determinations are carried out, the technical standards to be achieved, and specific legal and policy considerations. There is also separate detailed guidance on near surface and deep geological disposal of solid radioactive waste.

The generic Environmental Permitting Guidance may be found on our EPP webpage.

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# 2. THE PERMITTING PROCESS

The Government's Core Guidance and our regulatory guidance notes describe the operation of environmental permitting. The permitting of nuclear sites follows the same model, with some RSR-specific considerations. We describe these RSR-specific considerations in this chapter.

The introduction of RSR into environmental permitting has resulted in some changes in terminology and definitions, and some changes to the application and permitting process. There is no reduction in standards for the protection of people and the environment from radioactive substances. Nor is there any change in the respective responsibilities of the HSE and the Environment Agency on nuclear licensed sites, or how we work together, which is set out in a Memorandum of Understanding. The change to environmental permitting does not alter the nature or scope of what we regulate under RSR. We continue to regulate these activities in relation to the management of radioactive materials and radioactive wastes.

Under RSR in general, we regulate the keeping and use of radioactive materials, and the accumulation and disposal of radioactive waste. We do not regulate other matters associated with the carrying-on of a radioactive substances activity, for example, noise and vibration, or energy efficiency. In some cases, we may set conditions in relation to the conventional (ie non-radioactive) properties of radioactive substances in order to replicate provisions of other legislation that would apply if the material were not radioactive, for example in relation to wastes being disposed of to land.

### Licensees and Tenants: who to permit?

On a number of nuclear licensed sites, tenants occupy some buildings and conduct activities involving radioactive materials and producing radioactive waste.

The HSE regulates under the nuclear site licence on the basis that the licensee remains in control and supervision of such activities. However, we must permit the "operator" as defined in the Regulations and as set out in our "Understanding the meaning of operator" (RGN1 ). We must therefore consider who is conducting the undertaking in which the tenant is engaged. In some cases we may be able to agree that the undertaking is that of the licensee, and that the licensee is in control and making disposals under its authorisation.

However, if after consideration, we believe the tenant is conducting its own undertaking controlling the use of radioactive materials and disposing of radioactive waste, then we shall require the tenant to hold a permit for the relevant activities described in the next section.

The judgement on whether to separately regulate a tenant is made by our Nuclear Regulation teams on a case by case basis.

### What activities do we regulate on a Nuclear Licensed Site?

In environmental permitting, the former Radioactive Substances Act 1993 (RSA93) provisions for "keeping or use" and "accumulation" and "disposal" have been replaced by a number of "activities" as set out in schedule 23 of the EPR, where "activity" is a generic environmental permitting term to describe what is subject to regulation.

For a licensee, the principal activities are

*"where a person uses premises for the purposes of an undertaking and*

- *disposes of radioactive waste on or from those premises (Schedule 23 Part 2 5 (2(b)))*
- *receives radioactive waste for the purposes of disposing of that waste. " (Schedule 23 Part 2 5(4)*

We shall normally grant a permit to include both of these activities, to allow the transfer of wastes between sites for ease of disposal, unless the operator chooses not to be permitted for the receipt of waste.

The "keeping or use" of radioactive materials and the "accumulation" of radioactive waste on a NLS by a licensee are not activities regulated under the Regulations, since these are regulated by the HSE under the NIA site licence. Licensees do, however, need an environmental permit for any off-site use of "mobile radioactive apparatus", which is defined as:

*"any apparatus, equipment or appliance or other thing which is radioactive material and*

a) *is constructed or adapted for being transported from place to place : or*
b) *is portable and is designed or intended to be used for releasing radioactive material into the environment or introducing it into organisms." (Schedule 23 Part 2 5 (5)).*

The accumulation of radioactive waste on a NLS by a tenant is not an activity regulated under these Regulation but tenants do need a permit if they:

- *keep or use radioactive material;*
- *receive radioactive waste for the purposes of disposing of that waste;*
- *dispose of radioactive waste on or from the premises; or*
- *use mobile radioactive apparatus.*

There is a new activity, section 23 Part 2 5 (6) and (7), introduced with the Regulations, namely;

*"(6)…where a person carries out intrusive investigation work or other excavation, construction or building work*

a) *to determine the suitability of any premises, or*
b) *to enable the use of any premises,*

*as a place that may be used wholly or substantially for underground disposal of solid radioactive waste, subject to an environment permit allowing such disposal "*.

(7) In sub-paragraph (6)—

*"intrusive investigation work" means the drilling of boreholes into, or excavation of, sub-soil or rock to determine geological or hydrogeological conditions; and*
*"underground disposal" means—*

> *(a) the disposal of solid radioactive waste in an engineered facility, or in part of an engineered facility, which is beneath the surface of the ground, and*
>
> *(b) where the natural environment which surrounds the facility acts, in combination with any engineered measures, to inhibit the transit of radionuclides from the facility to the surface,*

*and does not include the disposal of radioactive waste in a facility which is beneath the surface of the ground only by virtue of the placing of rocks or soil above it.*

This has been introduced primarily for the proposed deep geological disposal facility, to ensure early regulatory engagement in its development. We may also apply this provision to other facilities for the disposal of solid radioactive waste (whether or not on a nuclear licensed site) in accordance with Government guidance.

## Water Discharge or Groundwater activities carried on as part of an RSR activity

The regulations allow certain activities to overlap, and for some activities to be carried on as part of another. This is described in Part 2 of RGN 2 "Understanding the meaning of regulated facility". The regulations allow water discharge activities and groundwater activities to be carried on as part of any RSR activity. However, a water discharge or groundwater activity will only be regarded as part of the RSR activity if it is integral to, or depends on, the RSR activity. If there are other discharges to water or groundwater which do not arise from the disposal of radioactive waste, then these will not be regarded as part of the RSR activity and will need to be permitted as standalone activities (or as part of an installation). This applies even if radioactive and non-radioactive effluents are discharged through a common pipe.

For example, on a nuclear power station there may be disposals of liquid radioactive waste to controlled waters. This would be an RSR activity with a water discharge activity carried on as part of it. In practice the liquid radioactive waste would most likely be discharged with other non-radioactive liquid discharges, such as cooling water. But the cooling water discharge would not be part of the RSR activity and therefore would require a permit as a discrete water discharge activity (or installation). In this situation it would be sensible to treat any non-radioactive content of the radioactive waste as part of the water discharge activity. If there is only an RSR activity, then that will need to consider any non-radioactive aspects of the discharge.

See below for other considerations in relation to Groundwater activities.

## Regulated facility and site

"Regulated facility" is a generic term which covers all types of activities and sites under EPR. Regulation 14 requires that permits *"must include a map, plan or other description*

*of the site showing the geographical extent of the site of the facility*". This requirement does not apply to permits in force before the 6th April 2010. Chapter 6 of the Core Guidance and RGN2 (Understanding the meaning of regulated facility) provide more information on the meaning of regulated facility and site.

The definitions of radioactive substances activity refer to the "premises used for the purpose of an undertaking". "Premises" is defined in the Regulations (schedule 23 xx) as *"premises" includes any land, whether covered by buildings or not, including any place underground and any land covered by water*". "Premises" may be interpreted as including all the land used by the operator for the purposes of the undertaking in question. (This was the approach formerly adopted under the Radioactive Substances Act 1993).

"Undertaking" refers to the wider business, process or activity undertaken by the operator, not the use of radioactive substances or the disposal of radioactive waste.

The "regulated facility" should include systems used for the disposal of radioactive waste up to the point of discharge to the environment or where they become the responsibility of another, for example pipelines to sea or controlled waters, or to a public sewer.

For licensees, the geographical extent of the regulated facility for the purposes of regulation14 should be taken to include:

- the area of the licensed site on the basis that this is licensed as a whole for the use of radioactive substances with the potential to generate and dispose of radioactive waste throughout and hence may be regarded as the premises for their undertaking – subject to the following;
- any adjacent systems (eg pipelines) outside the NLS used for the disposal of waste from the NLS; and any other adjacent areas outside the NLS used for radioactive substances activities to the extent these are carried out by the same operator and can reasonably be regarded as forming a single premises.

For tenants "site" will be defined by the extent of the premises used for their undertaking, including any systems for the disposal of radioactive waste. However, the definition of "premises" may be restricted to the land/buildings on which the radioactive substances activities take place. If adopting this more restrictive approach to the definition of premises, the operator must ensure that the description of the premises includes all the land used for the RSR activities from receipt of radioactive substances, through their use, to accumulation and disposal of radioactive waste as relevant. This is to allow for the ready movement of radioactive substances within the premises between areas where radioactive substances are received, stored, used and disposed of.

Where the HSE has issued more than one site licence to the same operator on contiguous sites we shall normally treat this as a single site and issue a single permit, unless the operator prefers to treat these as separate sites with separate permits.

The purpose of the above arrangements, is to define the area of the regulated facility (ie the premises) as required under Regulation 14(4). We only regulate those aspects of the facility on those premises for which we have regulatory vires.

The above paragraphs describe the approach to defining the area of an RSR activity and regulated facility. Each class of activity (eg installation, waste operation) has its own approach to defining "site". Where there is more than one regulated facility, the total site is made up of the footprints of the individual regulated facilities. We do not expect to issue consolidated permits covering RSR activities and other activities immediately but this remains an aspiration for the medium term.

The area of the regulated facility is defined through a permit condition and to change the boundary of the regulated facility, an operator must apply for:

- a variation to increase the size of the site, or
- surrender, or partial surrender, to decrease the size of the site.

We describe the provisions in relation to surrender below.

## Application Forms

The EPR require applications to be made on the forms we provide. We have developed a general purpose application form for the nuclear sector and shall consider, where appropriate, developing forms tailored to specific types of application, eg in relation to a geological disposal facility.

We have designed the RSR activity application forms to facilitate the use of supporting documentation that may have been prepared for other purposes. An applicant may decide to submit an application form and supporting documentation in electronic form, hard copy or both. We encourage submissions of the same documents to both the HSE and ourselves, where practicable.

The section on "Environment Cases" in Chapter 4 discusses some of the information we shall require operators to submit in their applications.

## Consultation on applications

The Public Participation Statement and RGS 6 (Determinations involving sites of high public interest) describe our policy on consultation and we have "working together agreements" with a number of bodies, describing when we shall consult them.

**Comment [EA1]:** Will add link here later

We shall advertise and consult on all applications for new permits except for those aspects where national security or commercial confidentiality restrictions apply. We may decide to do additional consultation, for example on a draft decision. We shall decide whether to consult on applications for variations, having regard to their environmental impact and the degree of public interest. We shall not consult on applications for the transfer or surrender of permits. Annex B gives more information on when and how we consult on applications.

## Time limits for determining applications

For a NLS, there is no statutory time limit for the determination of applications for new permits or transfers of permits by licensees or tenants. This is because we need to co-

ordinate our work with NII's work in assessing safety cases. The timescales for other applications are as follows:

- three months for an application to surrender a permit or vary it (other than where public participation is required);
- four months for an application to vary a permit where public participation is required.

This is a change from the RSA93 provisions, which did not specify a time limit for determining variations – although the EPR also allow such longer time periods as we may agree with the operator;

## Groundwater, Land Quality and surrender of permits

Under the EPR, there are separate statutory provisions in relation to groundwater (GW) and land quality, although in practice these are linked through the surrender provisions which require the site (including groundwater and the land) to be returned to a satisfactory state on surrender. The application of these provisions on nuclear licensed sites differs from that of other sites because of the provisions of NIA 65 and the nuclear site licence conditions.

Discharges of radioactive substances to groundwater may constitute a "groundwater activity" within the Regulations and Schedule 22 sets out the relevant provisions. In general, a groundwater activity occurs only where there is a planned and **permitted** direct or indirect discharge of radioactive wastes to groundwater (eg direct injection into groundwater or discharge to a soakaway with subsequent percolation to groundwater). The disposal of radioactive waste by burial is considered to be a groundwater activity. The regulation of any release of radioactive material to groundwater falls to the HSE.

The following do not constitute a groundwater activity under the Regulations

- potential and actual accidental releases, whether of radioactive substances or waste, into groundwater
- existing contamination of groundwater, whether on- or off-site.

Given the complexity of the provisions in the Regulations, Nuclear Regulatory Group staff must consult RSR National Technical Services if they consider that an operator on a NLS may be undertaking a groundwater activity as defined in schedule 22 of the Regulations.

The EPR include a provision for an operator to apply to surrender a permit, on permanent cessation of the regulated activities - although there is no obligation to do so. An operator may apply to surrender the permit for all the regulated activities or partial surrender covering only the regulated activities that have ceased. If an operator wishes to reduce the extent (area) of the premises permitted then it must apply for partial surrender to do so.

Schedule 5, 14(1) sets out two tests in relation to surrender:

(a) to avoid a pollution risk resulting from the operation of the regulated facility; and

(b) to return the site of the regulated facility to a satisfactory state, having regard to the state of the site before the facility was put into operation

These tests have been disapplied for radioactive substances activities on nuclear licensed sites for licensees and tenants, on the grounds that such matters are the primary responsibility of the HSE, and shall be dealt with by the HSE through the site licence or as part of de-licensing, for which we are consultees. De-licensing is a separate process from surrender and our role in that is not covered by this guidance. For radioactive substances activities, operators on NLS will not be required to make and keep a site condition report as defined in RGS9 (Demonstrating land and groundwater are protected to assist the surrender of an environmental permit ) and H5 (Site condition report – guidance and templates) and will not need to meet the tests for surrender of a RSR environmental permit. This disapplication applies in relation to RSR activities to the regulated facility as a whole, including any parts of the facility which may be outside the NLS boundary.

However, alongside the disapplication of the surrender tests, we expect the operator to take the necessary measures to avoid contamination of land and groundwater during the operation of the site, remediate any contamination that does occur, and restore the site to a satisfactory state. The operator should do this as part of the routine management of the facility and should maintain the necessary records as part of the routine management arrangements Section 5.6 of the REPs provides further guidance. How these matters are addressed in practice need to be discussed and agreed with the HSE on a site by site basis recognising its vires and Site Licence conditions. Under the revised Nuclear Sector Plan, we expect operators to develop land quality management plans.

**Comment [RY2]:** Insert link?

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**Disposal of radioactive waste by burial**

There is separate guidance on near surface and geological disposal of solid radioactive waste by burial.

# 3. PRINCIPLES of RADIOLOGICAL PROTECTION

In this section we describe the principles of radiological protection, based on the recommendations of the International Commission on Radiological Protection (ICRP). The DECC RSR guidance explains how these principles are incorporated into European and UK law and we describe how these are implemented in practice through the EP regime in section 4. We have described these principles here because they, and the relevant legislation and Government policies, lead to a number of RSR-specific regulatory requirements and approaches to the permitting of RSR activities in general and nuclear licensed sites in particular

The current legislation and practices are based on the *1990 Recommendations of the International Commission on Radiological Protection (ICRP60)*. ICRP is a non-governmental scientific organisation which has been publishing recommendations for protection against ionising radiations for several decades. These were re-affirmed, and their application to disposals of radioactive waste clarified, by ICRP Publication 77 *(Radiological protection policy for the disposal of radioactive waste, adopted by ICRP in May 1997*).

In December 2007, ICRP published its 2007 Recommendations, which update the 1990 Recommendations. The new Recommendations do not present a change in radiological protection objectives but aim to take account of new biological and physical information and of trends in setting radiation safety standards. ICRP has also aimed to improve and streamline the presentation of the Recommendations. The Health Protection Agency (HPA) has reviewed and published its conclusions on the "Application of the 2007 ICRP recommendations to the UK" . The 2007 Recommendations have not at present been adopted into UK policy and legislation.

For all human actions or practices that add to radiation exposure, the system of protection recommended by ICRP in its 1990 Recommendations is based on the following principles:

(a) no practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes (the justification of a practice). ICRP 60 states that: 'The Commission recommends that, when practices involving exposure, or potential exposure, to radiation are being considered, the radiation detriment should be explicitly included in the process of choice. The detriment to be considered is not confined to that associated with the radiation - it includes other detriments and the costs of the practice. Often, the radiation detriment will be a small part of the total. The justification of a practice thus goes far beyond the scope of radiological protection.ICRP77 states that: 'The Commission's definition of the justification of a practice requires only that the net benefit of the practice, including the waste management, be positive. The selection of the most appropriate practice goes beyond the scope of the Commission's recommendations." In the UK decisions on justification are a matter for Government under the "Justification of Practices involving ionising radiation regulations 2004" SI 1769 – see para 1.9 and 3.11 of the

Government RSR Guidance. We shall only grant a permit if the practice has been accepted as “justified” by the Government

(b) in relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals ('dose constraints'), or the risks to individuals in the case of potential exposures ('risk constraints'), so as to limit the inequity likely to result from the inherent economic and social judgements (the **optimisation** of protection);

(c) the exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible to control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit (individual dose and risk **limits**).

Dose limits are set at a level intended to prevent those radiation effects in humans which are known to occur above a certain level or threshold of dose (deterministic effects) and to ensure that the incidence of those radiation effects for which it is assumed that there is no threshold and that the risk of causing the effect increases with the level of the radiation dose (stochastic effects) is not at an unacceptable level. Application of the optimisation principle and the use of constraints, which are set below dose limits, further reduces this risk to as low as reasonably achievable.

ICRP uses the term 'intervention' to describe those human activities which decrease overall exposure to radiation by removing existing sources of exposure, modifying pathways of exposure, or reducing the number of exposed individuals (e.g. actions to deal with an accident that has released radioactive material to the environment, or with unacceptably high levels of natural radiation). Intervention can be either at the source of the exposure or in the environment, where it may for instance restrict individuals’ freedom of action. The system of protection recommended by ICRP for such situations is based on the following principles:

(a) the proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention;
(b) the form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised.

The document Principles for the Assessment of Prospective Public Doses sets out principles and guidance for the assessment of ionising radiation doses to the public arising from planned discharges to the atmosphere and to the aquatic environment. The results of assessments undertaken in accordance with these principles and guidance will be used as an input into the process of determining whether discharges of radioactive waste to the environment should be authorised. This document has been developed by

the Environment Agencies in collaboration with the HPA and the Food Standards Agency (FSA).

In addition, we shall also carry out an assessment of the doses to reference flora and fauna that might arise from discharges at the proposed limits.

A full framework for radiological protection of non-human species is still under development. In the meantime, we have developed, in collaboration with English Nature (now Natural England) and the Countryside Council for Wales, an interim assessment approach. This uses models of the behaviour and transfer of radionuclides within ecosystems to predict environmental concentrations, from which the radiation doses to reference organisms can be estimated. The approach is set out in:

- *Impact Assessment of Ionising Radiation on Wildlife* (Environment Agency R&D Publication 128, 2001 (updated March 2003)); and *Habitats Regulations for Stage 3 Assessments: Radioactive Substances Authorisations* (Environment Agency R&D Technical Report P3-101/SP1a, 2003).

These doses can then be compared to 'guideline values' to assess the level of risk to flora and fauna. The EC funded FASSET project concluded that the threshold for statistically significant effects on individual organisms is about 100 microGy/hour. Allowing for the dose rate from natural background, which is at most about 60 µGy/h in European ecosystems, we have adopted a value of 40 µGy/hr as an assessment threshold below which no further regulatory attention is warranted.

The interim assessment approach was developed primarily to enable us to meet our obligations under the Habitats Regulations but can also be used to demonstrate that proposed discharges will not have a significant impact on other designated areas and ecosystems in general. The more recent EC funded ERICA project has developed the approach further. The results of the ERICA project are being incorporated into our assessment framework. The outputs from the ICRP's Committee 5 will also be taken into consideration during our assessments.

# 4 . RADIOLOGICAL PROTECTION AND OPTIMISATION IN PRACTICE

## Statutory and permit requirements

In this section we describe how the principles of radiological protection, that is justification, optimisation and compliance with limits, are implemented through the environmental permitting regulations. As already noted, the issue of justification is a matter for Government. The requirements for optimisation (ALARA) and dose limits are set out in Part 3 of Schedule 23 of the Regulations, which implement the corresponding requirements of the Basic Safety Standards Directive (BSSD), namely

*1 In respect of a radioactive substances activity that relates to radioactive waste, the regulator must exercise its relevant functions to ensure that—*

*(a) all exposures to ionising radiation of any member of the public and of the population as a whole resulting from the disposal of radioactive waste are kept as low as reasonably achievable, taking into account economic and social factors; and*

*(b) the sum of the doses resulting from the exposure of any member of the public to ionising radiation should not exceed the dose limits set out in Article 13 of the Basic Safety Standards Directive subject to the exclusions set out in Article 6(4) of that Directive.*

*2(1) In exercising those relevant functions in relation to the planning stage of radiation protection, the regulator must have regard to the following maximum doses to individuals which may result from a defined source—*

*(a) 0.3 millisieverts per year from any source from which radioactive discharges are first made on or after 13 May 2000; or*

*(b) 0.5 millisieverts per year from the discharges from any single site.*

*3 In exercising those relevant functions, the regulator must observe the following requirements of the Basic Safety Standards Directive—*

*(a) in estimating effective dose and equivalent dose, Articles 15 and 16;*

*(b) n estimating population doses, Article 45; and*
*(c) in relation to the responsibilities of undertakings, Article 47*

These requirements are placed on the regulator. We give effect to these requirements through permit conditions. The optimisation requirement (ALARA) is achieved through the use of the following permit conditions. These are based on Government's requirements set out in the Statutory Guidance concerning the regulation of radioactive discharges into the environment.

*2.3.1 The operator shall use the best available techniques to minimise the activity of radioactive waste produced on the premises that will require disposal of on or from the premises..*

*2.3.2 The operator shall use the best available techniques in respect of the disposal of radioactive waste pursuant to this permit to:*

(a) *minimise the activity of gaseous and aqueous radioactive waste disposed of by discharge to the environment;*
(b) *minimise the volume of radioactive waste disposed of by transfer to other premises;*

(c) *dispose of radioactive waste at times, in a form, and in a manner so as to minimise the radiological effects on the environment and members of the public.*

These conditions taken together with any specific conditions in relation to the use of best available techniques deliver the provisions in the Regulations about optimisation and the corresponding provisions of the BSSD. We use other permit conditions to give effect to the other requirements arising from Article 47 of the BSSD.

**Use of BAT**

In this and other guidance, we describe the measures or techniques that an operator uses or proposes to use to achieve an optimised outcome as "best available techniques" (BAT). BAT has, through the recent Statutory Guidance, replaced the predecessor terms of "best practicable means" (BPM) and "best practicable environmental option" (BPEO) in England and Wales. Ministers have stated in the Statutory Guidance to the Environment Agency on "the regulation of radioactive discharges into the environment" that BAT will "deliver the equivalent level of environmental protection as achieved until now by the use of BPM and BPEO"

There is no statutory definition of BAT as it applies to RSR activities. The Statutory Guidance explains that Ministers consider the Pollution Prevention and Control (PPC) and Oslo and Paris Convention (OSPAR) definitions of BAT to be essentially the same. The DECC RSR guidance adopts the OSPAR BAT definition and we shall use that definition in our permits. Annex A provides the OSPAR definition.

The adoption of BAT in RSR does not mean that:

- in general, the requirements of the PPC Directive have been applied to RSR; nor
- specifically, the approach to BAT is the same in both regimes.

There are significant differences between how BAT is determined in PPC and RSR, because of the different legal and policy requirements of these regimes. There is also a wide body of detailed technical standards developed for PPC through the European "BREF Notes", which are a requirement of the PPC Directive. Such European standards are not currently available for RSR. In RSR, we use a principle-based approach and are developing this further through the REPs and other supporting guidance. Adoption of BAT is not intended to change practices within RSR. Consequently, differences will remain between RSR and PPC in how BAT is approached and demonstrated

**What does "optimisation" involve in practice**

The principle of optimisation applies specifically to radiological risks to people in every situation where radiation could cause damage or harm. 'Optimisation' (keeping exposures as low as reasonably achievable) applies only to radiological risks to people. Other living organisms must also be protected from radiological hazards but there is no optimisation requirement.

Optimisation decisions balance the detriment or harm associated with the radiological risk, together with other benefits and detriments (economic, human, societal, political, etc.) associated with disposing of the radioactive waste, both at the time the decisions

are taken and in the future, and the resources available for protecting people and the environment. Optimisation decisions are constrained by the circumstances prevailing at the time and must take into consideration and be consistent with the relevant legislation and Government policies. Optimisation needs to be viewed as part of a bigger picture, recognising that there will be competing claims for limited funds, and that there is no completely risk free way of managing radioactive waste. The result of optimisation provides a radiological risk at a suitably low level, but not necessarily the option with the lowest possible radiological risk. Dose limits and constraints are aimed at ensuring that the radiological risk is at a suitably low level.

'Optimisation' means that judgements have to be made about the relative significance of various issues, including:

- the number of people (workers and the public) and other environmental targets that may be exposed to radiological risk;
- the chance they could be exposed to radiation, where exposure is not certain to happen;
- the magnitude and distribution in time and space of radiation doses that they will or could receive;
- nuclear security and safeguards requirements;
- issues similar to those above, but relating to non-radiological hazards;
- economic, societal and environmental factors;
- technical viability;
- uncertainties in any of the above.

Within the wider field of radiological protection, different regimes use different terminology and have their own guidance on this topic, eg reducing risks as low as reasonably practicable (ALARP) (HSE), use of best practicable means (BPM) and best practicable environment option (BPEO) (previously in the UK but now only in Scotland and Northern Ireland) and now best available techniques (BAT) in England and Wales. However, all of the above involve the same process, ie making a judgement between options by comparing benefits in terms of safety, environmental protection etc, and costs in terms of time, effort or money.

## Guidance on the process of optimisation

We have provided general guidance on the process of optimisation in our RSR Principles of Optimisation document. In standard EPR terminology, this would be called "risk assessment". However, for consistency within the field of radiological protection and with other regulators, we refer to this as optimisation and the use of BAT, where BAT is the range of techniques whose use delivers an optimised outcome. We have developed a principles-based approach to optimisation to:

- give operators flexibility to develop joint or integrated assessments which cover worker safety as well as environmental impacts (ie address our and HSE's requirements together in a single document);
- allow cross-border operators to use a common approach in Scotland and in England and Wales.

Our guidance; RSR Principles of Optimisation, together with the other guidance on options appraisal and the assessment of radiological impacts, sets out how operators

should approach optimisation and the selection of BAT. There is also separate detailed guidance on near surface and geological disposal facilities for solid radioactive waste.

## Scope of optimisation : scope of conditions 2.3.1 and 2.3.2

The requirement for optimisation covers all aspects of the carrying-on of an activity leading to the generation and disposal of radioactive waste, and BAT means both the " *technology used and the way in which the installation is designed, built, maintained, operated and dismantled"*

Therefore in principle these conditions apply to all aspects of nuclear site processes - not just waste management processes - which have a bearing on radioactive waste production and which thus relate to the foreseeable disposal of those radioactive wastes at some stage.

For example, these conditions would cover:

- The chemical conditioning of the primary coolant within a water-cooled nuclear reactor. This water is used to transfer heat from the nuclear fuel to the steam generators in the power station, and its precise chemical composition (which can be controlled by adding chemicals to it) can significantly affect corrosion within the reactor, and hence the radioactive waste arisings.
- The choice of materials used for the various component parts of a nuclear reactor. Although it is essential that the materials perform satisfactorily on safety and operational grounds, nevertheless there may be alternative materials for specific parts of a reactor which are both acceptable on those grounds and which can have a significant effect on the activity in the radioactive wastes that the reactor produces.
- The operation and maintenance of a pond water conditioning plant at a nuclear power station. (The pond is used to store irradiated nuclear fuel which has been discharged from the reactor, and it is not part of a waste disposal system). Good pond water chemistry and cooling are important with regard to BAT for the minimisation of waste: if the chemistry is wrong or the temperature increases then there is increased potential for fuel to corrode, so releasing activity into the pond water that will ultimately have to be removed through chemical treatment plant and/or filters, or by discharging it into the environment.

We shall apply these conditions within our vires on nuclear sites and as set out in Memoranda of Understanding and other agreed ways of working with the NII. That is, we shall apply these conditions only in relation to the goal and purpose of keeping exposures from waste disposals "as low as reasonably achievable" .

In relation to higher activity wastes we operate as set out in the "Fundamentals of the management of radioactive waste : An introduction to the management of higher-level radioactive waste on nuclear licensed sites" and associated guidance. This work is done through the NII site licence : we shall not duplicate this work through application of the BAT conditions.

## Demonstration of optimisation: Environment Case

Operators should maintain written demonstrations that they operate to meet relevant environmental standards and requirements, including Government policies, and have optimised the disposal of radioactive waste to reduce exposures to ALARA. This demonstration should include:

- how wastes will arise, be managed and disposed of during the lifecycle of the facility;
- the quantification of those arisings;
- their radiological impact; and
- how the production, discharge and disposal of these wastes is being managed to reduce their radiological impact on people to ALARA and to protect the environment (termed a "BAT report", for convenience).

Operators will, through these documents, set out their strategies for the management of radioactive waste. These strategies should be consistent with Government Policies and our guidance.

The "environment case" is the term we apply to the totality of documented information and records which substantiates the above high-level demonstrations and sets down how these are being implemented and delivered on a day-to day basis, including compliance with permit conditions. We do not require or expect operators to prepare and maintain separate documentation for this purpose, indeed we encourage operators to make use of documents prepared for other purposes and to take an integrated approach to safety and environmental matters. It is a matter for the operator to decide in what form it keeps this documentation. However, the operator must ensure that the documentation, however structured, makes the above demonstrations in a transparent, structured and comprehensible manner.

The environment case is not a once-off series of documents prepared in support of an application for a permit or variation but a holistic, living framework which supports all environment-related decisions made by the operator.

We shall include a condition in the permit requiring the operator to maintain an environment case and to review and, where necessary, revise it in the light of:

- changes in legislation or policy;
- new facts or new knowledge about impacts on people and the environment;
- technical developments;
- when processes or operations change eg from operating to decommissioning

- where any of these could have significant impact on the management and disposal of radioactive waste, on people and the environment, or compliance with permit conditions. The operator should use this review and revision process to identify when it will be necessary to apply for a variation to the existing permit.

We have designed the application forms accordingly. The supporting guidance to the application form gives detailed guidance on the information to be provided. The operator will need to provide the necessary information when applying for a new permit, and to provide updated information to cover any changes when applying for a variation. Applications must contain sufficient information to allow them to be determined : we do not expect operators to submit the totality of their environment case.

We may also ask the operator to submit a revised BAT report on his operating techniques, including other information about disposals;

- when notified by the operator of changes in the environment case, (where these changes do not lead to an application for variation) and
- as part of or following our review of the permit.

We may ask for submission of a BAT report and associated information on all or part of the facility.

All submissions of the BAT and other information, whether part of an application or provided through the permit conditions, will be placed on the public register, subject to national security and commercial confidentiality restrictions**.**

# 5 REGULATORY REQUIREMENTS IN RELATION TO PERMITTING AND PERMIT CONDITIONS

This chapter describes certain legal and policy requirements which we must take into consideration when permitting, in particular where these differ from previous practices under RSA93.

## Receipt and Disposals of radioactive waste.

The EPR have removed certain provisions in RSA93 in relation to informing local authorities about waste transfers and disposals. It is no longer necessary in most cases to identify in the permit the specific site where waste will be disposed of. Permits may allow transfer to any site where the operator of that site holds a permit to receive, accumulate or dispose of radioactive waste. (In some cases, e.g. for disposals of Low-Volume Very Low Level Waste, the receiving site may not require a permit).

These changes do not otherwise alter the basis of our regulation. Operators must continue to demonstrate that their proposals for waste disposal, including off-site transfers, represent an optimised approach for all disposals (as in Chapter 3) and take into account relevant Government policy requirements such as use of the waste hierarchy and the proximity principle. In permitting disposals, we shall normally:

- specify how waste is to be disposed of (eg solid waste to incineration) ; and
- set limits and conditions on the amount and nature of the waste, where appropriate.

We retain the discretion to identify a specific consignee site for accumulation and/or disposal of radioactive waste as necessary to meet the requirements of Government policy.

## Permit conditions relating to BAT

The requirement for optimisation and the use of BAT to achieve ALARA are ongoing, and operators must deliver them in day-to-day operation. We shall place conditions in the permit requiring use of BAT; this is not a change as these are essentially the same conditions as the previous conditions regarding the use of BPM.

### Setting discharge limits based on BAT

We set discharge limits, based on the use of BAT by operators, at the minimum necessary levels to allow “normal” operation or decommissioning of a facility. Limits will be based on the routine expected level of discharges from normal operation of the facility using BAT, with the minimum headroom to cover relevant operational fluctuations, trends and events that are expected to occur over the likely lifetime of the facility. If there are predictable changes in discharges over the lifetime of a facility, limits should be set, and from time to time varied, so as to continually exercise control as described above. Limits should not be set on the basis of the predicted worst case discharges over the lifetime of the facility, if these are not expected to arise during current operations.

"Normal" is dependent both on what the facility is designed to manage and what discharges are likely to result from activities undertaken over the lifetime of the facility. It is the responsibility of the operator to identify the relevant fluctuations, trends and events affecting discharges, and to request and justify sufficient allowance to allow discharge limits to be set as described above.

Flexibility in setting discharge limits may be necessary in those cases where key Government objectives need to be met. Such objectives include, for example, the safe and timely decommissioning of redundant facilities, clean-up of the historic legacy of radioactive wastes, security of energy supply including through permitted new nuclear build, maintaining defence nuclear and non-nuclear capabilities, and the use of radionuclides in medicine.

When considering the limits on discharges to the environment to be included in a permit, we shall carry out an assessment of the doses to members of the public that might arise from the discharges at the proposed limits using the approach described in Principles for Prospective Dose Assessment. This is to ensure that the doses are consistent with the dose limits and dose constraints. The Environment Agency will consult the FSA on the terms of any permit that we propose to grant for a nuclear site. The FSA's response may include its own assessment of doses to members of the public.

As set out in the Statutory Guidance, where the prospective dose to the most exposed group of members of the public is below 10 μSv/yr from the overall discharges of an regulated facility, we shall not seek to reduce further the discharge limits that are in place, provided that the holder of the environmental permit applies and continues to apply BAT

The 10μSv/y figure is not a dose target, or a dose limit, or a threshold, or a radiation standard. It merely represents an appropriate level of dose, below which discharge limits need not be reduced further if the operator is continuing to apply BAT. This has superseded the "threshold for optimisation" of 20 μSv/yr set out at paragraph 73 of Cm 2919, *Review of Radioactive Waste Management Policy – Final Conclusions,* July 1995.

# 6 NEW NUCLEAR POWER STATIONS

It is likely that any application we receive for a new nuclear power station will relate to a design that has been through, or is going through, our Generic Design Assessment (GDA) process (as described in our *Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs*). By introducing GDA, we have, effectively, split our assessment process for new nuclear power stations into two phases: the first – GDA – addressing generic design matters, and the second dealing with applications for a specific site. The outcome of our GDA is a 'Statement of Acceptability' about the design, which may have exclusions or conditions attached to it. We shall take full account of this in considering an application for a specific site. This means that we shall not repeat work already done in GDA, but shall focus on operator-specific and site-specific matters, any relevant changes to the design, and how the applicant has addressed the exclusions and conditions attached to the statement

# ANNEX A DEFINITION OF BAT

BAT is defined as

*The use of the best available techniques shall emphasise the use of non-waste technology, if available.*

*The term "best available techniques" means the latest stage of development (state of the art) of processes, of facilities or of methods of operation which indicate the practical suitability of a particular measure for limiting discharges, emissions and waste. In determining whether a set of processes, facilities and methods of operation constitute the best available techniques in general or individual cases, special consideration shall be given to:*

a) *comparable processes, facilities or methods of operation which have recently been successfully tried out;*

b) *technological advances and changes in scientific knowledge and understanding;*

c) *the economic feasibility of such techniques;*

d) *time limits for installation in both new and existing plants;*

e) *the nature and volume of the discharges and emissions concerned.*

*It therefore follows that what is "best available techniques" for a particular process will change with time in the light of technological advances, economic and social factors, as well as changes in scientific knowledge and understanding.*

*If the reduction of discharges and emissions resulting from the use of best available techniques does not lead to environmentally acceptable results, additional measures have to be applied.*

*"Techniques" include both the technology used and the way in which the installation is designed, built, maintained, operated and dismantled.*

# ANNEX B WORKING TOGETHER

We shall advertise and consult on all applications for new permits in accordance with our Public Participation Statement and the Working Together Agreements with other organisations. As nuclear sites meet the general criteria of being sites of High Public Interest we must also consider the appropriate extent of any additional consultation both on the application itself and when we have decided our draft proposals. We have accordingly decided to consult additionally on both the application and our draft proposals for all applications for new permits on nuclear sites. However the extent of consultation will depend on the significance of the site and the nature of the facility being permitted. Thus for example we shall consult 'nationally' on a new major nuclear waste repository and 'locally' on a small research laboratory.

We may choose whether to consult on applications for variations, and where we make variations to the permit. To ensure a proportionate approach is adopted for any proposed variation we shall have regard to the significance of the site and the nature of the proposed variation. On the basis of this consideration we determine whether to consult and the extent of consultation. For example we shall consult ' nationally' on a proposed major increase in emission limits on the most significant sites, 'locally' on such increase on 'minor sites and not at all for minor changes not affecting limits on all sites.

# GLOSSARY AND ACRONYMS

| Term | Meaning |
|---|---|
| Activity | A generic title for the practices or operations which require to be permitted (unless exempted from the need for a permit). |
| ALARA | As Low as Reasonably Achievable (economic and social factors being taken into account).<br>Radiation doses comply with ALARA when they have been reduced to a level that represents a balance between dose and other factors (including economics). This is a statement of the optimisation principle. |
| BAT | Best Available Techniques - see annex for full definition |
| BPEO | Best Practicable Environmental Option |
| BPM | Best Practicable Means. |
| BSSD | Basic Safety Standard Directive (96/29/EURATOM) |
| DECC | Department of Energy and Climate Change<br>This is the Government Department with policy responsibility for Radioactive Substances Regulation in England |
| Defra | Department for the Environment, Food and Rural Affairs<br>This is the Government department with specific responsibilities for EPR. |
| EPR | Environmental Permitting Regulations |
| FSA | Food Standards Agency. |
| GRA | Guidance on Requirements for Authorisation<br>Environment Agency guidance detailing the environmental objectives which an underground facility for the permanent disposal of radioactive waste must achieve. There are two versions of the GRA: one for geological disposal of higher activity radioactive waste; and one for near-surface disposal of lower activity radioactive waste. |
| GW | Groundwater (specifically in relation to a groundwater activity under the Regulations) |
| HSE | Health and Safety Executive<br>Regulator with responsibilities for, amongst others, IRR99 and NIA65. |
| HPA | Health Protection Agency |
| ICRP | International Commission on Radiological Protection |
| ILW | Intermediate Level Radioactive Waste |
| Justification | The benefits and detriments of any practice which could result in exposure to ionising radiation must by assessed prior to the practice being permitted. If the benefits outweigh the detriments, the practice is justified. |
| LLW | Low Level Radioactive Waste |

| Term | Meaning |
|---|---|
| LVV-VLLW | Low Volume Very Low Level Radioactive Waste |
| Licensee | An operator licensed under NIA65 |
| NIA65 | The Nuclear Installations Act 1965 |
| NII | Nuclear Installations Inspectorate |
| NLS | Nuclear Licensed Site : a site licensed under the Nuclear Installations Act 1965. |
| Options assessment | Any formal and recorded method by which the 'best' solution is determined from a number of possible alternatives. |
| OSPAR | Oslo and Paris Convention for the protection of the marine environment in the north-east Atlantic.<br>The UK is a signatory to this Convention, which commits the UK to reducing discharges of pollution, including radioactive substances, to the sea and hence reducing marine concentration of pollutants. |
| Proximity principle | This means enabling waste to be disposed of in one of the nearest appropriate installations by means of the most appropriate methods and technologies in order to ensure a high standard of protection to the environment and public health. |
| Regulated facility (RF) | A collective term for the range of activities permitted under the Environmental Permitting Regulations |
| REP(s) | Radioactive Substances Regulation – Environmental Principles. Environment Agency guidance which sets out, at a high level, the principles which the Environment Agency applies to RSR. |
| RSR | Radioactive Substances Regulation |
| SAP(s) | Safety Assessment Principles . HSE guidance which sets out, at a high level, the principles which the HSE applies to safety cases. |
| Sustainable Development | Development which meets the needs of the present without compromising the ability of future generations to meet their own needs. Specific to radioactive waste, the Government's policy is to 'ensure that radioactive waste is managed safely and that the present generation, which receives the benefit of nuclear power, meets its responsibilities to future generations'. |
| Tenant | An operator on a nuclear licensed site but who is not a licensee.. |
| Waste Hierarchy | A principle of waste management which requires that (in order of preference) wastes be:<br>• Avoided<br>• Minimised<br>• Reused<br>• Recycled<br>• Disposed of |