



Scottish Environment Protection Agency

Framework for Risk Assessment for Landfill Sites

The Geological Barrier, Mineral Layer
and
the Leachate Sealing and Drainage System

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1. Introduction and Scope

- 1.1. This document provides guidance for Agency operational staff on the procedure for risk assessment at all landfill sites regulated by the Scottish Environment Protection Agency in relation to the geological barrier, mineral layer and leachate sealing and drainage system requirements of Annex I of the Landfill Directive. This document may also be provided to operators and designers as guidance to the Agency's requirements for risk assessment submissions. The procedures described may be applied to both existing and new landfill sites.
- 1.2. This guidance provides a framework for undertaking landfill risk assessments in relation to the Landfill Directive and does not cover the details of risk assessment techniques. It is necessary when reviewing a landfill site risk assessment that Agency officers contact the Area Hydrogeologist who will provide assistance in reviewing risk assessments in relation to groundwater. Furthermore the stability of the lining systems must be reviewed in order to ascertain that the geological substratum is sufficiently stable to prevent settlement that may damage the liner system. This is a requirement of the Landfill Directive. For advice on this aspect officers should contact the Landfill Directive Implementation Team.
- 1.3. This guidance is to be applied to all landfill site classifications. When assessing the containment requirements of a landfill site the requirements of both the Landfill Directive and the Groundwater Directive must be met. It is, for example, possible for a site to meet the requirements of the Landfill Directive solely in terms of the prescriptive containment requirements but such measures may not provide sufficient protection in terms of the Groundwater Directive or the Water Framework Directive. The procedure described here builds on the methods formerly used under Regulation 15 of the Waste Management Licensing Regulations 1994 etc and includes a consideration of new issues introduced by the Landfill Directive. The overall objective of the risk assessment framework is to allow landfill site barriers to be determined in accordance with the Groundwater Directive, Water Framework Directive and Landfill Directive.
- 1.4. This document only provides a framework of the key steps to be undertaken and it is assumed that readers are already familiar with the procedure of risk assessment formerly carried out to meet Regulation 15 of the Waste Management Licensing Regulations 1994. It is recommended that for further details on risk assessment the following are also referred to:
 - Directive 80/68/EEC (The Groundwater Directive).
 - The Groundwater Regulations 1998
 - Directive 2000/60/EC (The Water Framework Directive)
 - IPPC Sector Guidance for Landfill Sites
 - The Pollution Prevention and Control (Scotland) Regulations 2000
 - A Practical Guide. Issue 2
- 1.5. Any queries that SEPA staff have on the use of this guidance should be directed to Alex Garden, Robert Silver or any other member of the Landfill Directive Implementation Team.

2. Definitions and Framework for Assessment

2.1. Figure 2.1 shows a schematic diagram of a typical landfill site and indicates how the key terms of the Landfill Directive relate to the framework risk assessment to be used for landfill sites in Scotland.

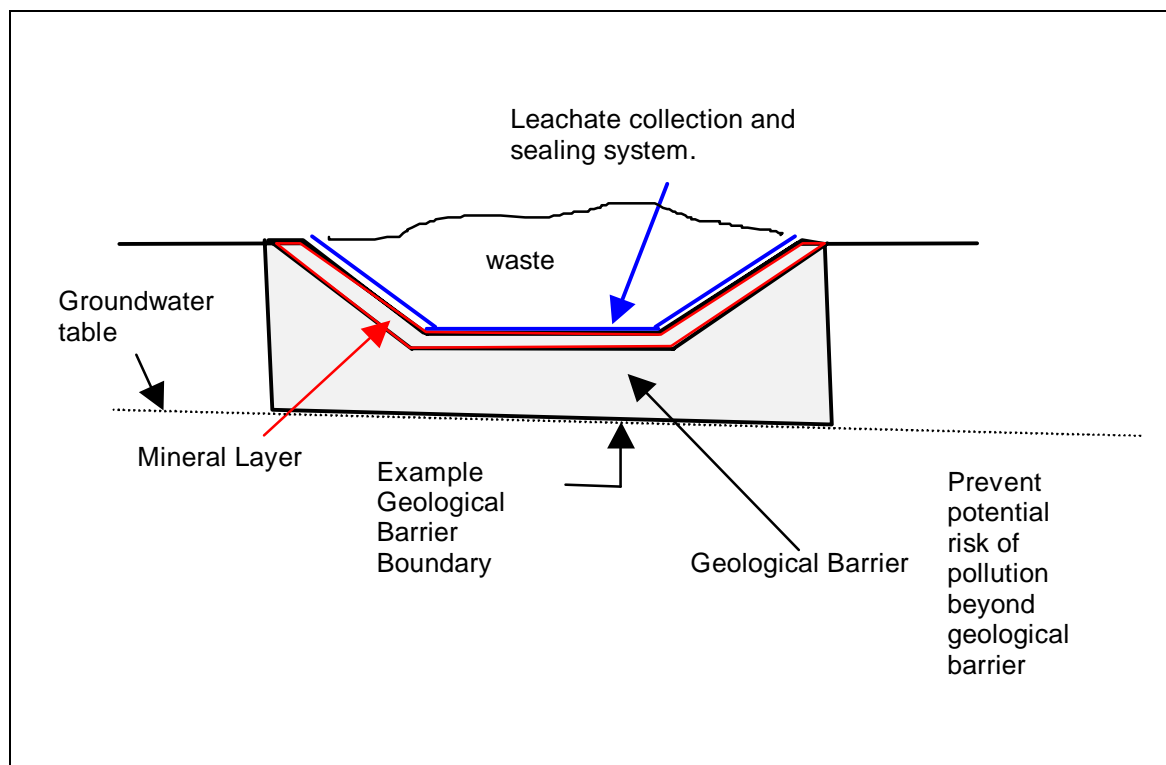


Figure 2.1 : Schematic diagram of landfill site and key terms

2.2. The key components referred to in the Landfill Directive are the geological barrier and the leachate sealing and collection system. These are considered below.

3. Geological Barrier

3.1. The Geological Barrier comprises 2 aspects:

- a low permeability mineral layer
- attenuation by surrounding geology /hydrogeology

3.2. The geological barrier is indicated in Figure 2.1 as a shaded area. The geological barrier comprises a mineral layer, which meets the permeability and thickness criteria in section 3.2 of Annex 1, and potentially other geological material, such as the unsaturated zone, which may provide attenuation below and in the vicinity of the landfill site. The low permeability mineral layer is required to extend over the base and the sides of the landfill.

3.3. The boundary of the geological barrier is to be established by the acceptable extent of a zone of attenuation below and in the vicinity of the landfill site. Beyond the boundary of the geological barrier the potential risk to groundwater or its associated receptors must be prevented. This boundary should therefore be analogous to a compliance point, beyond which the requirements of the Groundwater Regulations 1998 should be met. For example for list II substances it may be a

downgradient borehole at the edge of the site and for list I substances the compliance point would be the base of the unsaturated zone. The boundary should be defined by consideration of the type of contaminants and the geological and hydrogeological conditions on site.

3.4. The geological barrier must include a mineral layer which meets the permeability and thickness requirements in paragraph 3.2 of Annex 1. If these requirements cannot be met by the natural conditions on site the geological barrier requires to be artificially established to meet the Directive stated performance criteria. An artificially established geological barrier must be at least 0.5m thick.

4. Leachate collection and sealing system

4.1. This is required in addition to the geological barrier. It comprises two elements:

- Artificial sealing liner
- Drainage Layer \geq 0.5m thickness

4.2. The specification of these is to be determined from the hydrogeological risk assessment to ensure compliance with the Groundwater Directive, Water Framework Directive and best practice for liner construction. Leachate accumulation is to be kept to a minimum at the base of the site to minimise leakage from the site. The acceptable level of leachate accumulation is to be established from risk assessment. This is because the greater the leachate depth the greater will be the hydraulic gradient across the lining systems. A larger hydraulic head will mean increased seepages through the liner. A low risk site with a weak leachate and a high specification barrier may therefore have a greater depth of leachate (e.g. 1m) than a site in a high risk location (e.g. 0.5m).

4.3. The Landfill Directive does not state what materials should be used to form a drainage layer. SEPA will require that the specification and make up of a drainage layer be determined on a site specific risk assessment basis with the objective of ensuring leachate accumulation at the base of the landfill is kept to a minimum. It may be that a multi layer system using materials of different specification which could be adopted to provide the minimum 0.5m layer thickness depending on the outcome of site specific risk assessment. It is not considered that the full 0.5m thickness must comprise coarse aggregate in all cases. Multi-layer systems incorporating geosynthetic materials and/or suitable engineering materials selected from incoming waste streams (eg whole used tyres) may also prove appropriate on a site specific basis. However, it is felt that in order to comply with the Landfill Directive the minimum thickness of 0.5m will be required in all circumstances where leachate is to be collected and the site poses a potential hazard to soil, groundwater or surface water.

4.4. It is of note that the directive does not specify the materials to be used when forming a sealing liner. SEPA will require that the specification is determined based on risk assessment. The default material for a leachate sealing liner for a landfill that has the potential to generate leachate is a flexible membrane liner (eg HDPE overlain by protector geofabric). It may be that at some sites (e.g. an inert landfill that requires lining) clay could be used as a sealing liner if shown to be acceptable by risk assessment. However, this would require to be in addition to the mineral layer specified in the directive. In addition, to effectively form a 'seal' the permeability of the material used to form the sealing liner must be significantly lower than the mineral layer and offer a level of environmental protection at least equivalent to a Flexible Membrane Liner. A layer of material with a permeability of greater than or equal to the underlying mineral layer will not meaningfully reduce seepage rates from the site and could not reasonably be considered to be providing a 'seal'.

4.5. It should be noted that there is a specific requirement in the Directive that the leachate sealing liner is in addition to the geological barrier. Given that the mineral layer comprises a component of the geological barrier it is not possible for the same unit of material to be considered both a mineral layer and a leachate sealing system when carrying out a risk assessment.

5. Mandatory Standards

5.1. For sites where there is a potential hazard to soil, surface water or groundwater the risk assessment framework described in this guidance is to be adopted when assessing the barrier and liner systems for landfills. Most of the components and specifications of the components will be derived as part of the risk assessment. Typically non-hazardous sites will receive Biodegradable Municipal Waste and other such material which have the potential to produce leachate and pose a hazard to the environment.

5.2. For those sites where there is a potential hazard to soil, surface water or groundwater the following aspects however must be provided in a barrier system. The Landfill Directive only permits these components to be reduced in standard where the site poses no potential hazard to soil, surface water or groundwater.

- the landfill must have a drainage blanket that is at least 0.5m thick
- the landfill must have a leachate sealing system
- the landfill must have a geological barrier which must have a mineral layer which satisfies the permeability and thickness requirements stated in the directive or equivalent:
 - Landfill for hazardous waste $K \leq 1.0 \times 10^{-9}$ m/s; thickness ≥ 5 m,
 - Landfill for non-hazardous waste $K \leq 1.0 \times 10^{-9}$ m/s; thickness ≥ 1 m
 - Landfill for inert waste $K \leq 1.0 \times 10^{-7}$ m/s; thickness ≥ 1 m
- the mineral layer must extend under the base and up the sides of the landfill
- the landfill must be situated and designed so as to prevent pollution of the soil, groundwater or surface water

5.3. In addition to complying with the terms of the Landfill Directive the landfill must comply with the requirements of the Groundwater Directive and the Water Framework Directive. Meeting the prescriptive containment requirements of the Landfill Directive does not necessarily mean that the level of impact on the groundwater will be acceptable. It is therefore necessary to carry out a risk assessment for landfills to ensure that the terms of the Groundwater Directive and the Water Framework Directive are complied with. Where the minimum requirements of the Landfill Directive do not provide sufficient protection to the groundwater then additional containment measures will be required.

6. Stages of Assessment

6.1. The geological barrier and leachate collection and sealing systems should be designed to comply with the Landfill Directive, the Groundwater Directive (80/68/EEC) and the Water Framework Directive.

6.1.1. To comply with the Groundwater Directive a site must not allow the discharge of list I substances into groundwater or pollution of the groundwater by List II substances. On top of this the Landfill Directive specifically states that the mineral layer of the landfill liner must comply with specified permeability and thickness requirements unless the site does not pose a potential hazard to soil, groundwater or surface water.

6.1.2. In general, if the requirements of the Groundwater Directive are being met this will also meet the requirements of the Water Framework Directive. It must be noted, however, that the Water Framework Directive applies to all pollutants and is not confined to the substances listed in List I or List II of the Groundwater Directive. In brief, the requirement for non-listed substances is to prevent pollution at receptors associated with the groundwater, such as surface water ecosystems or wetlands which are dependant on the groundwater and to prevent an increase in treatment at abstractions used for human consumption. Significant and sustained upward trends in concentrations of pollutants will have to be reversed under the Water Framework Directive: it is therefore important that the authorisation will not exacerbate any situation such that restoration will be required at a later date.

6.1.3. The Water Framework Directive also has a requirement to prevent harm to receptors from changes to groundwater levels. Any proposal to meet the requirements of the Landfill Directive which would lower groundwater levels such that there would be harm to associated surface water systems or wetlands should be avoided.

6.2. The following steps outline the procedure which should be adopted when assessing the suitability of the geological barrier and leachate collection and sealing systems. This is an iterative process to establish the site specific arrangements and specifications that ensure that there is no potential risk of pollution and that the specific permeability and thickness requirements of the Landfill Directive are met. This process is based on modeling the landfill performance and could be carried out by using programs such as LandSim to refine the landfill design to give optimum environmental performance.

6.3. The steps to be undertaken are (see figure 3.1 for associated flow chart):

Stage A

Carry out desk study and site investigation to establish the geological, hydrogeological and other environmental conditions and considerations (e.g. depth to water table, permeability of the unsaturated zone etc) on site. The Landfill Directive states that a site must have a geological barrier and a bottom liner during the operational stage.

Assess whether the site poses a potential hazard to the environment. The Directive permits that if the landfill poses no potential hazard to soil, groundwater or surface water then the geological barrier and leachate collection and sealing requirements of the Directive could be reduced and a site specific design agreed. This should be based only on an assessment of the type of waste and the location. For example a landfill comprising only peat and topsoil, although classified as non-hazardous, may be considered to pose no potential hazard if it is in a non-sensitive location. However, the same waste landfilled adjacent to a salmonid river may pose a hazard via ferruginous emissions from, for example, the peat. It is well accepted that landfills which take biodegradable

waste such as municipal solid waste pose a hazard to the environment including groundwater, surface water and soil. It is for this reason that controls are needed at such sites. It is unlikely that biodegradable sites can reasonably be considered to pose no potential hazard to the environment. Whilst small remote sites may well pose a low risk this does not equate to no potential hazard. The Agency considers that typically all non-hazardous and hazardous sites will pose a potential hazard to soil, groundwater or surface water. Therefore for most sites the requirements of the Landfill Directive cannot be reduced.

Stage B

Step 1. Define the boundaries of the geological barrier naturally present on site. The base of this barrier is the point at which the requirements of the Groundwater Regulations should be met. (i.e. no entry of List I to Groundwater and no pollution of Groundwater by List II.) Further guidance on the requirements of the Groundwater Regulations is given in The Pollution Prevention and Control (Scotland) Regulations 2000 - A Practical Guide. Issue 2.

Step 2. The Landfill Directive requires that the geological barrier must include a mineral layer which surrounds the base and sides of the landfill. The mineral layer must satisfy permeability and thickness requirements which is at least equivalent to the following:

- Landfill for hazardous waste $K \leq 1.0 \times 10^{-9}$ m/s; thickness ≥ 5 m,
- Landfill for non-hazardous waste $K \leq 1.0 \times 10^{-9}$ m/s; thickness ≥ 1 m
- Landfill for inert waste $K \leq 1.0 \times 10^{-7}$ m/s; thickness ≥ 1 m

An assessment is required of whether a mineral layer will be present which matches both the permeability and thickness requirements as noted above (see appendix C for method of assessment). If a compliant mineral layer is present then proceed to carry out a hydrogeological assessment to determine if the site complies with the Groundwater Directive (step 4). Where the natural conditions below and surrounding the sides of the site do not satisfy these criteria an assessment is required to be carried out to establish if the artificially reinforced mineral layer is at least equivalent to the specified permeability and thickness criteria. This is outlined below.

Step 3. Equivalence is to be assessed by comparing the environmental protection provided by the proposed artificial mineral layer with the environmental protection provided by the Landfill Directive standards mineral layer (i.e. 1m @ 10^{-9} m/s). Environmental protection can be estimated by source-pathway-receptor risk assessment (i.e. LandSim) and establishing resultant environmental impact (i.e. contaminant concentration). This would ideally be carried out by undertaking a parallel risk assessment of both the proposed landfill design mineral layer (e.g. Bentonite Enriched Sand) and the Landfill Directive standard mineral layer (ie 1m @ 10^{-9} m/s). The environmental protection of the design mineral layer would require to be as good if not better than the Landfill Directive standards to be acceptable. Since the design mineral layer is to be equivalent in term of hydraulic conductivity and thickness only then degradation and attenuation (i.e. cation exchange capacity) cannot be considered in order to establish equivalence. Equivalence must be established solely on the impacts of varying the thickness and hydraulic conductivity, with all other factors being equal and then comparing the environmental impacts.

Step 4. A site may be found not to comply with the Groundwater Directive or the Water Framework Directive even if it does meet the thickness and permeability criteria mentioned in 3 above. Therefore once it has been established that a site meets the equivalence criteria the site must then undergo a hydrogeological risk assessment to establish if it meets the requirements of the Groundwater and Water Framework Directives. If the resulting concentrations of contaminants in the groundwater are above that which is permitted by the Groundwater Directive or receptors are at risk under the Water Framework Directive, then the site design should be altered so that the leachate collection and bottom sealing and geological barrier are designed to a higher specification.

Step 5. The final step is to check that the proposals are best practice. This involves consideration of many aspects including CQA, installation, operation etc. This is not discussed here and guidance on this aspect is given in other more detailed Agency guidance on engineering of landfill liner and leachate collection systems. Including:

- Earthworks on landfill sites: Guidance on the design, construction and quality assurance.
- The use of nuclear density gauges for compliance testing of earthworks on landfill
- Guidance on the use of geomembranes in landfill engineering
- Guidance on the geophysical testing of geomembranes for landfill engineering
- Guidance on nonwoven protector geotextiles for landfill engineering
- Guidance on bentonite enriched soils for landfill engineering
- Guidance on the use of geosynthetic clay liners in landfill engineering
- A methodology for cylinder testing of protectors for geomembranes: 'a performance test to determine the protection afforded to a geomembrane by a geotextile or other protective materials, in specific site conditions.'
- Use of tyres for landfill leachate drainage works

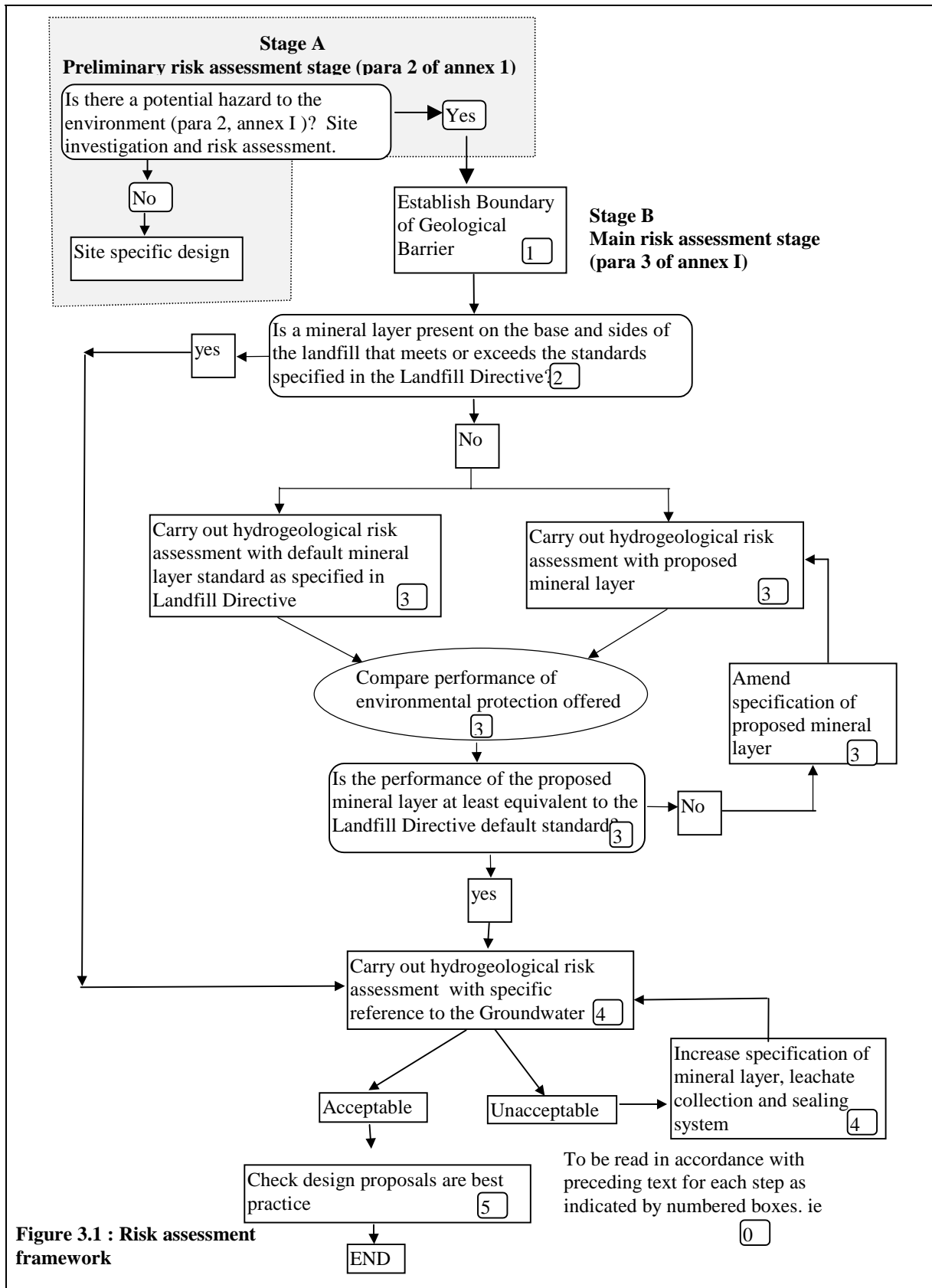


Figure 3.1 : Risk assessment framework

Appendix A: Modeling options

- A. 1 The Landfill Directive requires that environmental protection is provided by the geological barrier and bottom liner during the operational/active phase and a geological barrier and top liner during the passive phase/post closure. For the purposes of risk assessment the bottom liner can be considered to be the artificial sealing liner component of the leachate collection and sealing system.
- A. 2 The Directive requires that in the passive phase soil, groundwater or surface water remain protected. The protection is to be provided by the geological barrier and top liner (or capping system). A risk assessment should therefore consider the various states of the landfill over the whole life of the site considering both the operational/active phases and the passive/post closure phases. The risk assessment framework described in this guidance can be repeated for different scenarios to represent the whole life of the landfill site. For example during the operational phase a geological barrier and leachate collection and sealing system should be modeled based on uncapped infiltration rates whilst for the post closure phase it could be assumed that the leachate collection and sealing system is not operational but leachate generation would be based on capped infiltration rates and old waste deposits.
- A. 3 The risk assessment framework could also be used to assess environmental impacts from failure scenarios such as liner damage or failure of drainage system.

Appendix B: Reinforcement and equivalency

- B. 1 Where a geological barrier is to be reinforced to give environmental protection equivalent to the bench mark standards stated in the Directive the 'equivalency' from a environmental perspective will have been established in accordance with section 6 of this guidance. Modeling programs such as LandSim may or may not have been used to establish an 'equivalent' environmental protection but this should not take into account factors such as attenuation. However, there are other considerations that must be assessed when considering equivalency that are not accounted for in a model such as Landsim. This includes the physical robustness of the mineral layer which must offer the same performance as the bench mark criteria in the Directive.
- B. 2 For example a 1m layer of clay with a permeability of less than 1×10^{-9} m/s provides a degree of physical robustness in relation to penetration of objects. Furthermore when constructed under a CQA regime in multiple layers there is an inherent degree of redundancy (or safety) from areas that may be below standard when constructing a mineral barrier to a 1m thickness. During construction the robustness of a 1m clay liner also increases confidence in its ultimate environmental performance as it is less susceptible to construction induced damage.
- B. 3 Each landfill will require to be considered on its own merits in this respect as the site setting, operational techniques and wastes will vary from one site to another. To achieve equivalency it may be that the operational and construction techniques should be varied to reduce the risk of physical damage to an artificial liner. This could include controlling waste types, deposition rates, compaction, post construction leak detection (resistivity) surveys etc.
- B. 4 'Piggybacking' of liners over waste deposits can pose difficulties especially when considering the effects of settlement on a leachate collection and sealing system. This method of containment for a landfill will be considered on a site specific basis. Depending on the age and depth of waste it may be possible for parts of landfills to be developed on a 'piggyback' basis. Where a proposal is received to develop a site on a 'piggyback' basis officers are asked to contact the Landfill Directive Implementation Team to assess the proposals against the requirements of the Landfill Directive. It is considered that 'piggybacking' would only be acceptable at sites that pose a very low hazard to the environment.

Appendix C

Determining permeability coefficient for mineral liners

Interim Guidance on Determination of the Permeability Coefficient for Mineral Landfill liners and barriers.

C. 1 Introduction

1.1 Paragraph 3.5 of Annex I of Council Directive 1999/31/EC on the landfill of wastes states:

'The method to be used for the determination of the permeability coefficient for landfills, in the field and for the whole extension of the site, is to be developed and approved by the Committee set up under Article 17 of this Directive'

1.2 The following guidance has been produced to provide interim guidance to Agency officers on the method that is to be relied upon pending the issue of an agreed method from the Committee. A standardised method is required due to the prescriptive permeability criteria stipulated in the Directive.

1.3 The guidance is not a comprehensive review of permeability testing methods but is a statement of the interim method that is acceptable to the Agency.

1.4 In summary the method for determining the permeability is to use laboratory measured values on samples obtained in the field set within a Construction Quality Control and Assurance framework that provides a high level of confidence that the laboratory values are representative of the field permeability for the whole extension of the landfill site. This process is well established in the UK and is currently the best current practice for determining permeability of mineral liners.

C. 2 Scope of application

2.1 The Directive requires that the method be developed to determine permeability in the field and for the whole extension of the site. There are, however, a number of components that require permeability determination for landfill sites including:

- hydrogeological conditions at the site
- the geological barrier (natural condition or artificially completed condition)
- mineral layers used on the bottom or surface of the landfill
- drainage layers
- waste mass (eg for retro-installation of leachate abstraction wells)

2.2 Permeability is determined for different reasons in each case and different techniques will be employed depending on site specific conditions. Permeability determination must be carried out in each case in accordance with relevant CEN or British Standards specifically with reference to BS 5930 and BS 1377.

2.3 This interim guidance covers only the permeability determination in relation to the prescribed values of permeability set in the Directive which apply to the mineral layer component of the geological barrier.

C. 3 Permeability coefficient

3.1 The permeability of any mineral barrier is dependent on a number of variables including:

- Particle size distribution
- Particle shape and fabric of the soils
- Soil density (degree of compaction)
- Soil structure (degree of consolidation)
- Moisture Content
- Nature of the permeating fluid
- Mineralogy
- Variations in test type and procedure

3.2 In addition to the above variables the permeability of a mineral barrier is also affected by scale and construction dependent effects including:

- discontinuities in the barrier (natural condition or artificially completed condition)
- construction defects
- engineering failure of the barrier
- flow between clay clods
- desiccation

3.3 For this reason the field permeability of a mineral barrier for the whole extension of a landfill site will often be higher than that determined in the laboratory on a small sample of the mineral material. This feature is well acknowledged within the landfill industry and the practice of relying on engineered barriers formed under construction quality control and assurance procedures is primarily aimed at controlling and reducing the effect of these scale and construction dependent effects. By minimising these effects confidence can be gained that the permeability values established from small samples tested in the laboratory approach the field permeability for the mineral barrier as a whole.

C. 4 Determining the Permeability coefficient

4.1 It is not practicable to directly measure the permeability of a mineral barrier for the whole of a landfill site. However, the Directive calls not for a measurement technique but for a method of determining the permeability in the field and for the whole of the site. The permeability in the field can be determined by monitoring and controlling all the variables identified above although a direct quantitative measurement of certain variables such as discontinuities or construction defects is not practicable. However observation and control of these variables means they can be accounted for when making the determination. This interim method comprises a number of elements, these being;

- measurement of permeability in the lab of representative samples
- observation and control of barrier condition
- assessing and reporting on quantitative measurements and qualitative observations

4.2 This process should be carried out as part of the construction quality control and assurance procedure and should be subject to certification from an independent third party. For guidance on this process see Agency guidance 'Earthworks on Landfill Sites'. This method of determining permeability is in common with established UK industry practice which has developed in a direction to ensure, as best is practicable, that a uniform, homogeneous barrier is formed. This process aims to ensure that a high degree of confidence is obtained that the permeability values are representative of the whole barrier system.

- 4.3 In the laboratory, permeability should be measured in accordance with BS 1377 (1990), part 6, method 6. The sample should be a representative undisturbed sample of minimum dimension 100mm diameter by 100mm height. Effective stresses within the sample including those induced by hydraulic gradients and consolidation pressures must be representative of (and no greater than) the operational stresses to be experienced by the liner. This can be determined from waste fill rates and the final depth and density of the waste to be landfilled. For advice on this aspect Agency officers should contact the Landfill Directive Implementation Team.
- 4.4 There are in-situ techniques that can occasionally be used to estimate field permeabilities. These include ring infiltrometers and flooded test pads. However, these methods are primarily for use in research applications or on test pads of materials during design of a liner. They are not suitable for use in routine testing of permeability during the construction phase of a barrier or liner.

C. 5 In-situ geological barriers - mineral layer

- 5.1 The Directive quotes a permeability and thickness criteria for the mineral component of the geological barrier. There is no established method for determining in the field the permeability of a natural geological barrier for the whole of landfill sites. The main issue is the potential presence of hidden natural variations or discontinuities in the barrier. This potential for the presence of fractures (in rock) and lenses or layers of materials of a permeability higher than the main natural geological deposit means only a very low degree of confidence can be gained that samples taken from the barrier and tested in the laboratory are representative of the whole extension of the site. For this reason UK standard practice for many years has been to excavate and re-engineer insitu barrier materials under a CQC/CQA regime to increase confidence in the permeability of the barrier and this is currently best practice. For geological deposits that are highly homogeneous and fully characterised it may be possible to be confident that the insitu permeability meets that of the Landfill Directive throughout a 1m depth. Such deposits may be found on continental Europe and certain areas of England. In such areas depending on the homogeneity, permeability and thickness insitu mineral layers can occasionally be found to be acceptable on a site specific basis but in general reworking may be required. However, the deposits typically found in Scotland are generally characterised by a degree of heterogeneity (sand layers, fissures, etc) and for this reason most clay liners are formed from re-worked materials under a CQA regime.
- 5.2 Permeability values quoted for barriers which have not been laid in accordance with an engineered CQC/CQA regime will not be accepted by the Agency as being representative of the field permeability for the whole extension of the site. In such an instance the permeability coefficient will therefore be deemed to have not been determined for the purposes of establishing regulatory compliance.