HM Government

Information Sheet 1: Overview of the risk assessment process

About this Information Sheet

This Information Sheet provides background material on the analysis and interpretation of the findings of an investigation of land contamination under *Part 2A of the Environmental Protection Act 1990* and the *Statutory Guidance* (Department for Environment, Food and Rural Affairs (DEFRA) 2012). It should be used in conjunction with the method statement entitled 'Analysis and Interpretation Methodology for the Soil Investigation at Grenfell Tower'.

References to specific paragraphs of the *Statutory Guidance* (DEFRA 2012) are included in the text to help understanding (for example, SG 4.24, means paragraph 4.24).

Overview of the risk assessment process

This is a summary of the risk assessment process, which is based on a number of sources including DEFRA and Environment Agency (2004) and Environment Agency (2019). Please refer to Environment Agency (2019) and the wider range of technical guidance for detail on specific matters.

For there to be a risk, there must be a source of contamination, something or someone that could be harmed – termed a receptor – and a pathway through which receptors can be exposed to contaminants. The source-pathway-receptor relationship is called a contaminant linkage. A contaminant linkage that poses a '*significant possibility of significant harm to human health'* is called a '*significant contaminant linkage'* (SCL) and represents unacceptable risk under *Part 2A*.

The three tiers of risk assessment are:

- Preliminary risk assessment - first tier of risk assessment that develops the outline conceptual site model and establishes whether there are any potentially unacceptable risks given the specific legal context (in this case, *Part 2A*).
- Generic quantitative risk assessment – the second tier is carried out using generic screening criteria (See Information Sheet 2) and assumptions to assess risk.
- Detailed quantitative risk assessment – the third tier is carried out using further site-specific information including site-specific assessment criteria to assess risk.

Risk assessment is a complex iterative process. It normally follows the above sequence of tiers, but depending on the level of risk, you might not need to complete all steps. For example, if you conclude that there are no '*significant contaminant linkages'* after generic quantitative risk assessment there is no need to proceed to detailed quantitative risk assessment.

Overview of preliminary risk assessment

The preliminary risk assessment establishes whether, under *Part 2A*, there are any potentially unacceptable risks arising from contamination at the site. The specific activities undertaken include

- Define overall management objectives
- Collate and review current and historical information about the site and the potential contaminants expected to be present
- Carry out a site walkover and collect exploratory soil samples (while not normally the case for most sites, this activity has been undertaken as part of the Stage 1 investigation at Grenfell)
- Develop an outline conceptual site model
- Identify any potential '*contaminant linkages'*
- Identify uncertainties and gaps in information
- Qualitatively assess each '*contaminant linkage'* in terms of whether there is a reasonable possibility that it could be a '*significant contaminant linkage'*

At the conclusion of the preliminary risk assessment, the report will include:

- A summary of the objectives
- An outline conceptual site model
- Qualitative risk assessment of any potential *contaminant linkages*
- List of linkages for which there is a reasonable possibility that they could be a '*significant contaminant linkage'*

If there is no reasonable possibility of an unacceptable risk and no critical gaps in information then the process may be completed.

Overview of generic quantitative risk assessment

The purpose of generic quantitative risk assessment is to establish whether GSC (see Information Sheet 2) and assumptions are appropriate for assessing the risks and, if so, to apply them to establish whether there are potential unacceptable risks that can be ruled out, and if not, whether further detailed quantitative risk assessment is required.

The specific activities undertaken for a generic quantitative risk assessment include:

- Review and confirm the management objectives
- Define the specific objectives for this tier
- Collate a set of appropriate GSC (existing and bespoke) or use consistent methods of assessment such as a margin of exposure approach (COC 2018)
- Identify any additional information about site conditions that are required to apply the GSC (for example, soil pH or organic matter content)
- Design and implement an intrusive investigation to collect and analyse soil samples
- Quantitatively compare representative soil concentrations with GSC and estimates of the *normal level* of the contaminant in soil (see Appendix A2 in the method statement). Estimates of contaminant intakes from soil exposure may also be calculated and compared with the total exposure from all environmental sources

At the conclusion of the generic quantitative risk assessment, the report will include:

- A summary of the objectives
- Factual findings of any investigations
- Findings of quantitative risk assessment carried out for any contaminant linkages
- An updated conceptual site model showing the remaining potentially significant contaminant linkages identified
- Identification of risks and uncertainties and justification for subsequent actions (usually at the third tier, but could proceed directly to risk management)

If there is not a reasonable possibility of an unacceptable risk and no critical gaps in information then the process may be completed.

Overview of detailed quantitative risk assessment

The purpose of detailed quantitative risk assessment is to establish and use more detailed site-specific information and criteria to decide whether there are unacceptable risks. It may be used as the sole method for quantitative risk assessment or it may be used to refine a second tier assessment. This tier may be iterative with the collection of additional information to refine information gaps and uncertainties identified at an early stage.

The specific activities undertaken for a detailed quantitative risk assessment include:

- Review and confirm the management objectives
- Define the specific objectives for this tier
- Identify any additional information about site conditions that are required to carry out the detailed quantitative risk assessment (for example, additional soil samples, bioaccessibility tests, soil vapour samples, analysis of samples of fruit and vegetables)
- Design and implement an investigation to collect and analyse the relevant media samples and to collect any other additional information on the condition of the land and its use
- Derive a set of appropriate site-specific assessment criteria (these criteria may apply to media other than soil) or use consistent methods of assessment such as a margin of exposure approach or other tools or information as lines of evidence
- Quantitatively compare representative sample concentrations with site-specific assessment criteria. If sample concentrations are from soil then they can also be compared with estimates of the normal level of the contaminant in soil. Estimates of contaminant intakes from exposure may also be calculated and compared with the total exposure from all environmental sources and available dose-response information for the contaminant (such as an evaluation of pivotal studies, uncertainty factors, available or bespoke benchmark dose modelling, and assessments by expert toxicologists)

At the conclusion of the detailed quantitative risk assessment, the report will include:

- A summary of the objectives
- Factual findings of any investigations
- An updated conceptual site model and the *contaminant linkages* identified

- Quantitative risk assessment of any '*contaminant linkages'*, including a clear recommendation of which of the Categories (1 to 4) each linkage falls into
- Identification of risks and uncertainties and justification for subsequent actions

The local authority has the sole responsibility for deciding whether to determine any land as *contaminated land* relying on advice provided in the report or by another body. The starting point for this is to decide whether there is a '*significant possibility of significant harm'* to human health and which Category (1-4) each '*contaminant linkage'* falls into.

For '*contaminant linkages'* considered to fall in Category 1 – the land may be determined as *contaminated land* by the local authority and further intervention will be required. For '*contaminant linkages'* considered to fall in Category 4 – the land is not *contaminated land* and the *detailed inspection* is completed if there are no critical gaps in information.

For '*contaminant linkages'* that are considered to fall into either Category 2 or 3, the local authority decides first whether or not there is a strong case for considering that the risks are of sufficient concern. Where a strong case exists then the '*contaminant linkage'* will be considered to fall into Category 2 and the land may be determined as '*contaminated land'*. Where the local authority considers that the strong case does not exist then the '*contaminant linkage'* will fall into Category 3, where the risks are considered not low, but the land is not '*contaminated land'*.

If the local authority cannot make a decision on this basis alone, it may consider other factors which are relevant to achieving the objectives set out in Section 1 of the *Statutory Guidance*, including the factors listed in SG 4.27.

In Category 1 or Category 2, the timeframe for determining the land will be dependent on the situation. In all cases the local authority must notify interested parties first. The local authority may also postpone the determination of land if the land owner or some other interested person undertakes to deal with the problem. Once the land is determined, the local authority has a duty to require *appropriate persons* to carry out remediation by issuing a *Remediation Notice* unless voluntary action is undertaken. The local authority also has powers in specific circumstances to carry out works and recover costs where appropriate.

References

COC, 2018. Cancer risk characterisation methods, COC Guidance Statement G06 – version 1.1. Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/803675/G06_Cancer_Risk_Characterisation_v1.1.pdf

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