Application of environmental risk analysis at contaminated sites

Laura D'Aprile^(a) and Emiliano Scozza^(b)

^(a)Settore Siti Contaminati, Agenzia Nazionale per la Protezione dell'Ambiente e per i Servizi Tecnici, APAT, Rome, Italy ^(b)Dipartimento di Ingegneria Civile, Università degli Studi "Tor Vergata", Rome, Italy

Summary. Contaminated sites represent a challenge for all European Countries. Clean-up strategies currently focus on a risk-based approach for the definition of remediation goals. Many of the technical standards developed for the application of risk assessment at contaminated sites do not take into account the risk posed to human health by sediment contamination in a common framework. The present paper describes the technical procedure for the application of human health risk assessment at contaminated sites developed and recently updated by the National Environmental Agency and Technical Services (APAT) of Italy, according to the suggestions of a working group, coordinated by APAT, and composed by members of the main Italian scientific institutes (ISS and ISPESL) and of the Italian Regional Environmental Agencies (ARPA). Furthermore the main issues posed by the application of human health environmental risk analysis to contaminated sediments are discussed

Key words: risk assessment, contaminated sites, Italian guidelines, sediments.

Riassunto (*Applicazione dell'analisi di rischio ai siti contaminati*). La gestione dei siti contaminati rappresenta una sfida per molti paesi europei. Le strategie di bonifica dei siti contaminati sono attualmente focalizzate su un approccio basato sulla valutazione del rischio, per la definizione degli obiettivi di bonifica. Molti degli standard tecnici sviluppati sull'analisi di rischio non contengono indicazioni circa la valutazione del rischio per l'uomo legato alla presenza di sedimenti contaminati all'interno di un sito. Il presente lavoro descrive la procedura tecnica per l'applicazione dell'analisi di rischio ai siti contaminati sviluppata e recentemente aggiornata dall'Agenzia Nazionale per la Protezione dell'Ambiente e per i Servizi Tecnici (APAT) nell'ambito del gruppo di lavoro formato da ISS, ISPESL e da esperti delle Agenzie Regionali per l'Ambiente (ARPA). Vengono inoltre discusse le principali problematiche legate alla valutazione del rischio per i sedimenti contaminati. *Parole chiave:* analisi di rischio, siti contaminate, linee-guida italiane, sedimenti.

INTRODUCTION

Contaminated sites represent a challenge for all European countries. Clean-up strategies currently focus on a risk-based approach for the definition of remediation goals. The use of environmental risk analysis in contaminated site management is mainly due to the lack of funds available for the remediation of an increasing number of sites.

In many of these sites soil, subsoil, groundwater, surface water and sediments are contaminated at potentially harmful levels.

Technical standards for the application of human health environmental risk analysis at contaminated sites are available at US and EU level since early '90s and were subsequently improved. Many of these standards do not take into account the risk posed to human health by sediment contamination in a common framework. On the other hand, the problem of sediment contamination is taken into account in the ecological risk analysis evaluation that is currently not supported by consolidated standards at national level.

The present paper aims to present the technical procedure for the application of human health risk assessment at contaminated sites recently issued by the National Environmental Agency and Technical Services (APAT) of Italy, according to the indications of a working group, coordinated by APAT, and composed by members of the main Italian scientific institutes (ISS, ISPESL and ICRAM) and of the Italian Regional Environmental Agencies (ARPA). Furthermore the main issues posed by the application of human health environmental risk analysis to contaminated sediments will be discussed.

REGULATORY FRAMEWORK FOR THE APPLICATION OF ENVIRONMENTAL RISK ANALYSIS IN ITALY

According to the past Italian legislation on contaminated sites management and remediation [1],

Address for correspondence: Laura D'Aprile, APAT, Agenzia Nazionale per la Protezione dell'Ambiente e per i Servizi Tecnici, Settore Siti Contaminati, Via Vitaliano Brancati 48, 00144 Rome, Italy. E-mail: laura.daprile@apat.it.

the risk analysis procedure had to be applied when it has been demonstrated that, using the best available technologies at affordable costs (BAT), the concentration of the contaminant(s) cannot be reduced below the maximum allowable concentrations, set in Annex 1 of DM 471/99. In this case, risk analysis has to be applied in order to assess that the residual concentration(s), which can be achieved with the BAT, are acceptable in terms of human health and environment protection.

The Legislative Decree n. 152 issued in 2006 [2] by the Ministry of the Environment contains a new risk-based approach for contaminated site management, based on the partial application of the ASTM-RBCA procedure (without Tier 1) since the maximum allowable concentrations, set in Annex 1 of DM 471/99 are considered as screening levels. According to the indications of the Legislative Decree n. 152 of 2006, only Tier 2 (site-specific) assessment should be performed in order to develop site-specific target levels called CSR (concentrazioni soglia di rischio). The technical procedure set by Legislative Decree n. 152/06 is summarized in Figure 1.

The ASTM approach, (ASTM 1739, ASTM PS-104) [3, 4], *i.e.*, the RBCA (risk based corrective action) is characterized by a tiered approach. Tier 1 represents the screening step in the RBCA procedure, where the so called risk based screening levels (RBSL), are calculated applying the risk analysis with default non-site specific parameters and compared with the concentration(s) measured in the contaminated site. If the RBSL are exceeded, either remediation can be performed, or a Tier 2 risk analysis can be applied, which requires a further investigation effort.

In Tier 2, site-specific target levels (SSTL) are calculated, using site-specific data (fraction of organic carbon, permeability, porosity, source geometry, etc.), while also the migration scenario of the different contaminants are accounted for. The equations used in Tier 2 are of analytical type, often similar to those employed in Tier 1. The SSTL values are compared with the concentration(s) measured in the contaminated site. Again, it can be decided to perform remediation to these levels, or to perform a Tier 3 risk analysis, that requires a much more detailed characterization. In the latter case, new SSTL, based on a detailed and accurate description of the site characteristics (site geometry, variability, non-homogeneity) are calculated. Since characterization costs for a Tier 3 risk analysis may be prohibitive, very often the risk analysis activity is limited to Tier 2.

METHODOLOGICAL CRITERIA FOR THE APPLICATION OF ABSOLUTE RISK ANALYSIS AT CONTAMINATED SITES

The manual *Methodological criteria for the application of absolute risk analysis at contaminated sites* was developed by the University of Rome "Tor Vergata", following the indications of a working group, formed at the end of 2003, coordinated by the Italian National Environmental Agency (APAT), and composed by members of the main Italian scientific institutes (ISS, ISPESL and ICRAM) and of the Italian Regional Environmental Agencies (ARPA).

The first release of the document was published on the web site of APAT (www.apat.it) on June 2005, after its official presentation to the Ministry of the Environment and it has become a reference document for technicians of public administration, researchers, practitioners for the application of human health risk assessment at National Priority List Sites (NPLS). The latest revision was published on APAT website on March 2008 [5].

The manual refers to a Tier 2 analysis, according to the ASTM-RBCA standard and has been organized in order to provide a general view of the relevant references, the elements for building up the conceptual



model (source, pathways, receptors), the procedure for calculating both risk and site-specific target levels, the critical analysis of the most used software in Italy and the relevant validation criteria.

Besides, the issues concerning the presence of free product (NAPL), the criteria for the application of the Monte Carlo statistical approach, the sensitivity analysis on the different parameters. Together with the document on risk analysis, a database of chemical-physical and toxicological properties of the contaminants, developed by ISPESL and ISS, has been issued and periodically updated.

Site conceptual model definition

The first step in the risk analysis procedure consists in the definition of the preliminary site conceptual model (SCM), made by the elements source-pathway-receptor that shall be confirmed, revised and constantly updated with the information gradually available from characterization activities. In this step, the site general characteristics are also identified, including historical information, its geology and hydrogeology, meteorological data, etc. Besides, further investigation may be required in order to gather new data needed to complete the characterization dataset. Chapter 3 of the manual *Methodological criteria for the application of absolute risk analysis at contaminated sites* guides the user in the SCM construction according to the following steps:

- 1) source characterization;
- 2) contaminant migration;
- 3) exposure pathways and receptors.

Source characterization

The source characteristics in the framework of the site conceptual model are described in terms of selection of the contaminants and definition of their physico-chemical properties, source geometry, saturated and vadose zone geometric features, selection of the contamination source in either vadose or saturated zones, respectively.

Application of a Tier 2 risk analysis procedure [6], requires the selection of a single concentration representative value for each secondary contamination source (surface soil, deep soil, groundwater). Such a value is an input parameter, that is of primary importance for the correct implementation of the risk analysis procedure; it shall be determined following proper criteria, depending upon assumptions that may change as the approximation required is changed, type, number and significance of available data. Therefore, the main critical issue is constituted by the samples selection and the application of algorithms in order to obtain a representative and scientifically sound concentration value.

It is worth pointing out that, as a pre-requisite, the available analytical data-set must be already validated, *i.e.* outlier and non-detect have been already selected and properly treated. The procedure to be followed for the definition of source concentration is summarized in *Figure 2*.

The first issue is linked to the dataset dimension; namely, a statistical analysis of the dataset may be performed only if more than 10 data are available. Below this threshold, following the criteria of maximum conservativeness, the source representative concentration is set equal to the maximum experimental value. On the contrary, if the data set includes at least 10 values, they can be analyzed through statistical methods. In the latter case, it is first suggested to select the probability distribution that more closely matches the available dataset through the ProUCL software developed by USEPA [7]. The representative concentration is set equal to the UCL of the mean, determined by the same software.

Contaminant migration

The contaminants originally present in the contamination source may reach potential receptors through different migration pathways [6]. In the framework of a Tier 2 risk analysis procedure, the estimation of the concentration at the point of exposure is performed introducing proper transport factors:

$$C_{poe} = C_s \times FT$$

The general criteria followed for the selection of the equations allowing calculating the transport factors can be summarized as follows:

- the contaminants' concentration is assumed to be homogeneously distributed in the soil and to be constant through all the exposure period;
- soil is assumed to be homogeneous, isotropic and incoherent;
- the technical documents analyzed and compared for the transport factors estimation were the main national and international standard documents on risk analysis: ASTM 1739, ASTM PS-104, EPA Soil Screening Guidance [8, 9]. CONCAWE [10], Manuale Unichim 196/1 [11];



Fig. 2 | *Criteria for estimating the source concentration (Modified from Baciocchi* et al. [6]).

- the selection of the equation to be used for estimating each transport factor has been performed, taking in account the following criteria: significance, conservativeness and applicability to the Italian situation.

The equations used to determine the transport factors include several physical parameters relevant to the environmental compartment involved: vadose and saturated zone, indoor and outdoor air, surface water.

Exposure pathways and receptors

The exposure pathways represent the way through which a potential receptor may get in touch with the contaminants. Exposure is direct if the receptor is directly exposed to the contaminated matrix; it is termed indirect exposure, if the receptor gets in contact with the contaminant due to the migration of the latter to a given distance from the source. From a general view-point, the receptor may get in touch with contaminant, through exposure to:

- surface soil (SS);

- outdoor air (AO);

- indoor air (AI);
- groundwater (GW).

Different exposure pathways may be correlated to each contamination source; therefore, in different sites it is possible to have different combinations, depending upon the specific properties of the site. As far as the contamination target receptors are concerned, this work makes reference to human receptors only. Human receptors are identified in terms of the soil use, in the area affected by the contaminated site. In this document, three possible soil uses are considered:

- residential use, with adult/child human receptors;
- recreational use, with adult/child human receptors;
 industrial/commercial use, with adult human re-
- ceptors.

It is worth pointing out that child receptors represent human receptors up to 6 years old.

Exposure E [mg kg⁻¹d] is the chronic daily contaminant assumption. This factor is given by multiplying the concentration of the contaminant(s) at the point of exposure, C_{poe} , with the effective exposure rate EM that may correspond to the daily ingested soil amount, inhaled air volume or ingested water volume, per unit body weight:

$$E = EM \times C_{poe}$$

Estimating the effective exposure rate, EM, requires evaluating the daily dose of the contaminated matrix that is assumed by the human receptors identified in the conceptual model. The general form of the equation used to estimate the effective exposure rate EM [mg/kg/day] is as follows:

$$EM = \frac{CR \times EF \times ED}{BW \times AT}$$

It is worth mentioning that the symbol AT corresponds to the averaging exposure period for a human receptor to a given compound. This parameter is set to the average duration of the daily life (AT = 70 years), for carcinogenic compounds, whereas it is set equal to the effective exposure duration (AT = ED) for non-carcinogenic compounds.

The equations to be used for calculating the effective exposure rate for each exposure pathway are reported in *Table 1* [6]:

The use of any of the above mentioned equations requires the evaluation of the different exposure parameters corresponding to the human receptors that are being considered. The workgroup has selected the default value for each exposure parameter relevant to each exposure route, among those proposed by national and international standard documents and software.

These default values shall be used in a Tier 1 procedure but, in general, also in a Tier 2 risk assessment.

Risk calculation

The estimation of risk for human health (R), correlated to exposure to a contaminant, may be calculated by application of the following general equation:

$$R = E \times T$$

Where E ([mg/kg d]) is the daily chronic contaminant exposure rate and T ($[mg/kg d]^{-1}$) is its toxicity.

The individual risk is defined as the risk for human health associated to a specific exposure route to a single contaminant. Its determination is performed in a different way, depending on the type of effects (carcinogenic or toxic), that the given compound may have on the human receptor. Namely, in the case of carcinogenic compounds:

$$R = E \times SF$$

Where R (risk [adim]) is the life-long probability of incremental cancer case occurrence, caused by exposure to the contaminant, SF (slope factor [mg/ kg d]⁻¹) is the probability of incremental cancer case

Table 1 Equations used for calculating of exposure rate (Modified from Baciocchi et al. [6])
Soil dermal contact $EM = \left[\frac{mg}{Kg \ x \ giorno}\right] = \frac{(SA \ x \ AF \ x \ ABS \ x \ EF \ x \ ED)}{(BW \ x \ AT)}$
Soil ingestion $EM = \left[\frac{mg}{Kg \ x \ giorno}\right] = \frac{(IR \ x \ FI \ x \ EF \ x \ ED)}{(BW \ x \ AT)}$
Outdoor vapor and particulate inhalation $EM = \left[\frac{m^3}{Kg \ x \ giorno}\right] = \frac{(Bo \ x \ EFg \ x \ EFg \ x \ EFg}{(BW \ x \ AT)}$
$\label{eq:EM} \begin{split} & \text{Indoor vapor and particulate unhalation} \\ & \text{EM} = \left[\frac{\text{m}^3}{\text{Kg x giorno}} \right] = \ \frac{(\text{Bi x EFg x EF x ED})}{(\text{BW x AT})} \end{split}$

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occurrence per unit dose, E is the exposure, averaged to a lifetime exposure period (AT = 70 years).

For toxic, non-carcinogenic effects:

$$HQ = \frac{E}{RfD}$$

where HQ (hazard quotient [adim]) is an "hazard index", that provides a quantitative indication on how much the exposure to a given chemicals exceeds the maximum allowable or reference one, RfD (reference dose [mg/kg d]) is the estimation of the daily exposure rate that does not induce adverse effects on humans during the entire life, and E is mediated on the effective exposure period (AT = ED).

Carcinogenic or toxic effects due to the combined exposure to more than one chemical are still not clearly understood. Nevertheless, it is possible to make a conservative estimate of exposure to more contaminants by simply adding the risk (or the hazard index) of the single contaminants. It is worth pointing out that, assuming no synergic effects, this approach probably is an over estimation of the effective risk associated to exposure to multiple contaminants.

Finally, the work group has suggested calculating both risk and hazard index for human health, associated to the presence of one or more contaminants through different exposure routes, by adding the individual risks correlated to the single contamination sources (surface soil, deep soil, groundwater).

Criteria for risk acceptance

The work group, based upon the general safety principle and the indications of ISS [5], has set the tolerable risk values (individual and cumulative) for the carcinogenic chemicals equal to 10^{-6} for the individual risk (associated to exposure to a single compound and to a single exposure route) and 10^{-5} for the cumulative risk (associated to exposure to all chemical compounds to which exposure takes place and to different exposure routes).

The acceptance criteria for chemical species that have toxic effects on human health, consists in assuring that the effective dose assumed does not exceed the TDI or RfD. Therefore, both individual hazard quotient (HQ) and cumulative hazard index (HI) shall be lower than one.

The above mentioned criteria for risk acceptance were recently indicated in the update of the national regulation on contaminated sites (Legislative Decree n. 4/2008 amending the Legislative Decree n. 152/2006) [12, 2].

APPLICATION OF HUMAN HEALTH RISK ANALYSIS AT CONTAMINATED SEDIMENT SITES

According to the indication of USEPA [13], a human health risk assessment and an ecological risk assessment should be performed at contaminated sediment sites (*Figure 3*). In addition to considering human health risk from soil, subsoil, surface water, groundwater, according to the previously described procedures, risks from contaminated sediments should be evaluated.

Generally, the human health risk assessment should consider the cancer and non cancer health hazard associated with the following exposure pathways:

- ingestion of fish and other biota inherent to the site (*e.g.*, shellfish);
- dermal contact with contaminated sediment;
- incidental ingestion of contaminated sediment;
- inhalation of volatilized contaminants;
- swimming and surface water ingestion.
- Potential human receptors may be:
- recreational fishers;
- subsistence fishers;
- workers (*e.g.*, port authority workers, dredging activities workers, etc.);
- swimmers;
- birdwatchers;
- transient;
- off site consumers.

The greater difficulties posed by the application of human health risk analysis to contaminated sediment can be summarized as:





Fig. 4 | Elements potentially continuing or increasing risk in remedial alternatives.

- sediments are part of a complex, dynamic system;
- water and sediment move;
- gradients are steep;
- species are highly mobile;
- food webs can be complex.

The above described elements lead to a great heterogeneity of the source and variability (*i.e.*, migratory and foraging characteristics) of the species in the contaminated zone.

The use of probabilistic approaches (*e.g.*, Monte Carlo analysis, fuzzy logic, etc.) allows users to characterize uncertainty from heterogeneity and variability.

In the US Navy guidance *Implementation guide for assessing and managing contaminated sediment at navy facilities* [14] the users may find useful indications.

Trophic trace

The United States Army Corps of Engineers (USACE) also developed a stand alone tool for calculating the potential human health and ecological risks associated with bioaccumulation of contaminants in dredged sediments called Trophic trace 4.0. The user manual provides details on the equations in Trophic trace and provides the users manual for the Trophic trace assessment tool [15].

A companion document provides a management guide with a quantitative example of how the model can be used within the United States Army Corps of Engineers (USACE) tiered approach to dredged material management. This tool can be used to provide health- and ecologically-protective estimates of potential risk using results from sediment chemistry tests or 28-day bioaccumulation tests. Trophic trace implements a steady-state bioaccumulation model based on Gobas (1993 and 1995) for organics, while the uptake and trophic transfer of inorganic are modelled using empirical BCF or Trophic transfer factors (TTF). A prototype of the model is presented for two types of contaminants: metals (arsenic) and chlorinated organics (polychlorinated biphenyls or PCBs and DDD, DDE, and DDT). The model currently incorporates several example datasets for assumptions for human exposure, which are presented and discussed in this paper. The user can edit the

demonstration model parameters as well as create new models based on different fish species and different human and ecological exposure parameters based on site-specific conditions.

All of the algorithms incorporated in Trophic trace follow USEPA and USACE risk assessment guidance.

Risk assessment as a tool in remedial alternatives selection

The available risk assessment procedures usually do not take into account the evaluation of risks from remedial alternatives, since these risks may be difficult to quantify. The EPA RAGS guidance [16, 17] although mainly addressing human health risks, does note that remedial actions can alter or destroy aquatic and terrestrial habitat and advises that this potential for alteration or destruction has to be evaluated during the selection of remedial alternatives [13] (*Figure 4*).

Generally, the continuing and/or increased risks posed by the implementation of remedial alternatives are extremely site and remedial alternative specific and can be addressed to:

- creation of new exposure pathways;
- increased release of sediment contaminants;
- worker exposure;
- disruption of benthic community and subsequent unexpected changes in SCM.

Each remediation approach has its own uncertainties, related to the complexity of sediment environment, and potential risk. The use of risk assessment in the selection of redial alternatives is based on the concept of net risk reduction.

A definition of this concept was given by the committee on remediation of PCB-contaminated sediments [18].

All remediation technologies have advantages and disadvantages when applied at a particular site, and it is critical to the risk management that these be identified individually and as completely as possible for each site. For example, managing risks from contaminated sediment in the aqueous environment might result in the creation of additional risks in both aquatic and terrestrial environments. Removal of contaminated materials can adversely impact existing ecosystems and can remobilize contaminants, resulting in additional risks to humans and the environment. Thus, management decisions at a contaminated sediment site should be based on the relative risks of each alternative management action. For a site, it is important to consider "overall" or "net" risk in addition to specific risks.

Therefore, the application of risk assessment should concern not only the evaluation of potential risks related to sediment contamination in the present (preremediation) and future (post remediation) scenario, but also the evaluation of selection alternatives by calculating risks introduced by implementing the alternatives and net risk reduction. In this framework even a no-action alternative may be appropriate if net risk reduction is correctly evaluated.

CONCLUSION

A growing interest for risk analysis application has been observed in the last few years, also due to the decrease of economic resources for contaminated sites clean-up. This has motivated the scientific community to elaborate reference standard documents and software, making application of risk analysis easier for environmental engineers and practitioners. Despite the growing interest for its use in contaminated sites management, application of risk analysis for contaminated sediment management at national scale is made difficult by the lack of a clear and comprehensive procedure approved by control authorities.

The manual *Methodological criteria for application of absolute risk analysis to contaminated sites*, originated by the need of unifying the approaches followed for performing risk analysis on contaminated sites, represents a reference document for technicians of public administration, researchers, practitioners, performing or evaluating remediation projects where a risk-analysis procedure has to be conducted. Taking into account the recent publication by USEPA and USACE of procedures and tools for sediment risk assessment, APAT, in co-operation with other relevant scientific institutes, is working on the development of a standard procedure, for the calculation of human health risks posed by contaminated sediment at NPLS.

Submitted on invitation. *Accepted* on 3 June 2008.

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