G R A D I E N T
TRENDS
Risk Science & Application

Winter 2020
Issue 77

Risk Assessment for Infrastructure

By Grace I. Greenberg, M.P.H. and Julie Lemay, M.P.H.

Well-accepted risk assessment methodologies are available to manage potential hazards associated with repairing the country's aging infrastructure.

It is critical that potential human health and environmental risks be effectively managed for complex infrastructure projects, such as in the areas of transportation (*e.g.*, harbors/marinas, roads, rail, aviation), telecommunications, and energy production and distribution. With population increasing and the growing need to repair, update, and expand aging "fundamental facilities and systems" (*i.e.*, infrastructure) within the United States, the number of large-scale infrastructure projects is rising. These can be highly complex projects, which translates into a variety of contaminant release, exposure, and risk scenarios that can be addressed with well-established risk assessment principles.

Infrastructure projects can result in unique exposure scenarios…

The U.S. EPA's core risk assessment principles (hazard identification, dose-response assessment, exposure assessment, and risk characterization) can be used to characterize the nature and magnitude of risks to human and ecological receptors exposed to contaminants in a variety of situations. For construction, repair, and demolition activities characteristic of various infrastructure projects, these core risk assessment principles can be used to proactively minimize or manage risks.

Infrastructure projects can result in unique exposure scenarios due to spatial or temporal considerations based on the nature of the work. Some projects can result in the creation of localized microenvironments with transient elevated pollutant levels, while intermittent exposures are characteristic of some projects. Quantifying

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I N S I D E

Letter from the Editors

January 2020

Dear Colleague,

In this issue of *Trends*, we discuss new frontiers in risk assessment.

The first article discusses risk assessment in infrastructure, and some of the unique exposure scenarios that arise with these large-scale and complex projects. The second article is about evaluating human health and environmental risks associated with recycled products, specifically "beneficial use" assessments of building material containing coal combustion products. The third article discusses a risk assessment method performed on medical devices called extractables and leachables (E&L) testing, and describes ways scientists can characterize and address the uncertainties that come from this testing method.

Gradient contributors to this issue include Grace Greenberg, M.P.H.; Julie Lemay, M.P.H.; Andrew Bittner, M.Eng., P.E.; Ari Lewis, M.S.; Matthew Lewis, M.S.; and Dr. Joel Cohen. Our guest editor is Craig Heidrich, Founder and Managing Director of HBM Group, an Australian-based professional association management company, who discusses efforts in Australia to characterize naturally occurring radioactive materials (NORM) in coal combustion products and to comply with guidelines and regulations for NORM.

We hope this issue of *Trends* will give you new insights on these evolving applications for risk assessment methods.

Yours truly,

Chris Long, Sc.D., DABT and Kurt Herman, M.Eng., P.G.
clong@gradientcorp.com kherman@gradientcorp.com

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Risk Assessment for Infrastructure

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exposures for localized microenvironments can be challenging, and this is complicated by the need to account for changes in contaminant levels over time and the intermittent nature of potential exposures. For example, contaminant releases into the air during repair work in subway tunnels can generate a microenvironment with continuous exposure for workers and intermittent exposures to the general public waiting on enclosed subway platforms during their commute. Cyclical patterns of elevated exposures can also occur in this microenvironment: as subway cars enter the station, contaminants are resuspended into the air, and the resuspended dusts settle before the next subway car enters the station (see figure). Although all individual exposures are unique, exposures protective of an individual, including sensitive populations, can be calculated using the U.S. EPA's concept of reasonable maximum exposure that reflects the highest exposure reasonably expected to occur.

Exposure Receptors and Transient Sources of Airborne Dust Emissions in a Subway System Undergoing Renovations

Repairing aging infrastructure can result in contaminants in air that present challenges to dust management during active construction. Beyond the management of total dust levels, potential contaminants in construction-related dust include asbestos, respirable crystalline silica (RCS), lead, and other heavy metals that require specialized exposure modeling and mitigation techniques. For example, the U.S. Department of Transportation estimates that approximately 90,000 steel bridges are coated with lead-based paint due to its anti-rust properties, with older bridges having thicker coatings from multiple applications. Lead dust generated from repairing a bridge can settle onto nearby neighborhoods or enter the underlying water body, posing a potential risk to both human and ecological receptors from multiple exposure pathways. Evaluating all potential exposures and hazards helps avoid overlooking potential risks to workers and the public during infrastructure development projects.

Real-time monitoring is frequently used during infrastructure projects to provide continuous measurements needed for accurate assessment of potential exposures. These measurements are compared to risk-based screening levels, above which, adjustments may be made to minimize worker exposures. While real-time monitoring can provide continuous measures of certain contaminants, real-time monitoring is not available for others. For example, repairing concrete structures can result in the release of dust particles, along with RCS. While total dust levels can be monitored continuously at a project site, silica measurement requires laboratory analysis of time-averaged air samples, with turnaround times of at least a day. In the absence of real-time measurements for RCS, surrogate modeling based on the relationship between real-time total dust measurements and laboratory silica sampling results may be used to estimate short-term silica levels at which corrective measures may need to be implemented.

With the increased need to update and expand our infrastructure, risk assessment principles based on accepted U.S. EPA methodologies offer a well-established framework for considering the complex array of possible contaminants, receptors, and exposure pathways and managing all potential risks.

The authors can be reached at ggreenberg@gradientcorp.com and jlemay@gradientcorp.com.

By The Way...

Twenty to 40 workers died during the construction of the Brooklyn Bridge in the 1870s and 1880s of causes that are now unlikely due to major advancements in occupational safety and industrial hygiene that occurred in the 20th century.

Source: The History Channel.

Beneficial Use Assessment of Building Materials Containing CCPs

By Andrew Bittner, M.Eng., P.E. and Ari Lewis, M.S.

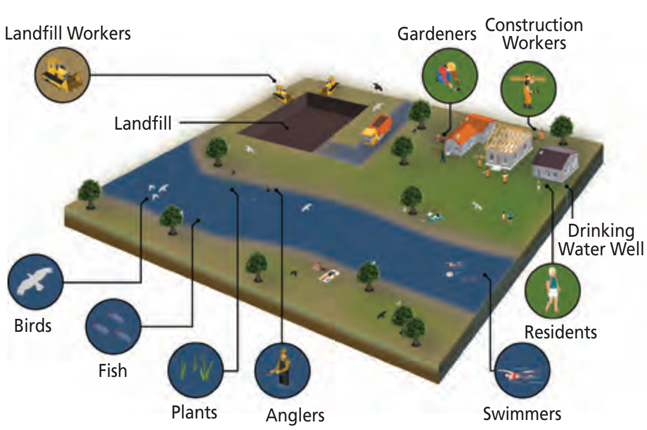
The U.S. EPA's guidance on beneficial use assessment utilizes well-established risk evaluation practices, as well as life-cycle analysis methods, to ensure protection of human health and the environment.

Beneficial use assessments are a special class of risk assessments that involve evaluating human health and environmental risks associated with recycled products. The term "beneficial use" originates from the benefits that are accrued by using recycled products rather than virgin materials; these benefits may include reduced use of natural resources, reduced greenhouse gas emissions, lower disposal costs, and improved functional characteristics for a new product or a new application. The reuse of coal combustion products (CCPs), that may otherwise be disposed in landfills, in building materials is a well-established beneficial use. While CCPs have been beneficially used for many decades, opportunities to expand current uses and develop new applications have emerged in recent years, partly due to federal regulations driving up CCP disposal costs.

Gradient has conducted several beneficial use assessments for various building materials containing CCPs.

Due to the increasing beneficial use of CCPs, federal and state agencies are attempting to define what qualifies as an acceptable beneficial use. Most notably, the U.S. EPA established four criteria in the 2015 Coal Combustion Residual (CCR) Federal Rule for the compliant beneficial use of CCPs. By showing compliance with the four beneficial use criteria, one can demonstrate that the use of CCPs provides a functional value without creating an unacceptable risk to human health or the environment. One criterion requires a demonstration in some circumstances that "environmental releases to groundwater, surface water, soil and air will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors." In 2016, the U.S. EPA developed a general methodology for conducting beneficial use evaluations and demonstrating compliance with the Federal CCR Rule.

Typical Human and Environmental Receptors Evaluated During CCP Beneficial Use Evaluation



The U.S. EPA guidance for beneficial use is not prescriptive but endorses several key principles. The approach is based on commonly accepted risk assessment practices and includes a life-cycle evaluation. For building materials, this means evaluating risks that may occur during installation of the product, during the active life of the product, and after the useful life of the product, when it has been disposed. The first phase of the assessment involves a planning/scoping step. Here, a conceptual exposure model (CEM) detailing all potential human and ecological receptors (see figure) and the pathways by which each receptor may be exposed is developed. This phase also includes an assessment of whether there are sufficient data available to evaluate possible exposures or whether new data need to be generated. A two-fold strategy is used to evaluate potential risks associated with the beneficial use of the product. The initial step is a screening analysis, where measured chemical concentrations in the building material or estimated soil, water, and air concentrations that are in contact with the building material are compared to established benchmarks that are protective of human health and the environment. If the established benchmarks are not exceeded, no further evaluation is necessary. If established benchmarks are exceeded, a more refined risk analysis is required incorporating site-specific and application-specific information. Finally, risk results and any uncertainties are reported during the risk characterization step.

Using this guidance, Gradient has conducted several beneficial use assessments for various building materials containing CCPs. For example, we evaluated the novel use of CCPs in house siding. Human receptors included those that could be potentially exposed to the products throughout its life cycle: construction workers, residents, recreators, and landfill workers. Ecological receptors that were considered in the evaluation included plants and organisms in soils or water bodies near where siding materials containing CCPs may be used.

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Risk Assessment of Extractables and Leachables in Medical Devices

By Joel Cohen, Sc.D., DABT and Matthew Lewis, M.S.

Despite some limitations, extractables and leachables testing has emerged as a valuable predictive toxicology tool for evaluating the safety of medical devices.

In the rapidly evolving regulatory landscape governing medical devices, extractables and leachables (E&L) testing is a vital step in ensuring biocompatibility, safeguarding patient safety, and establishing regulatory compliance. Such testing aims to characterize potential chemical exposures to the patient by using model solvents and exaggerated incubation conditions that mimic worst-case physiological conditions anticipated for the specific medical device (*e.g.*, orthopedic implant, surgical suture, hemodialysis machine). A comprehensive risk assessment of extractable chemicals can therefore be used to justify reducing the extent of *in vivo* testing required to establish medical device biocompatibility. However, the E&L process and subsequent toxicological risk assessment are not without uncertainty.

…even state-of-the-art analytical techniques cannot make definitive chemical identifications for all extractable compounds.

In some instances, even state-of-the-art analytical techniques cannot make definitive chemical identifications for all extractable compounds. For such cases, the amount of each "unknown" compound is compared against a threshold of toxicological concern (TTC), considered to be an allowable exposure level for potentially mutagenic compounds that would result in negligible risk of carcinogenicity to the patient. "Unknown" compounds are further evaluated for structural features associated with high potency mutagenic carcinogens referred to as the "cohort of concern" (*e.g.*, N-nitroso compounds, alkyl-azoxy compounds). Special scrutiny is given to these compounds, for which even the conservative TTC level may not be sufficiently health protective.

In addition to "unknown" compounds, there are often many unique or complex structures that lack complete toxicological data packages. While data gaps can be addressed through various means, best practices for using predictive tools have yet to be formally established. The ICH M7 guideline details an acceptable method for applying computational toxicology programs to predict mutagenic potential, which can then be applied to establish an appropriate TTC value. There are many readily available computational toxicology programs risk assessors can use that are suitable for complying with the ICH M7 method, though such computational programs must not be used as black boxes. Mutagenicity predictions should be evaluated by a trained toxicologist applying expert judgment to adequately support a risk conclusion that is based solely on computational methods. And while *in silico* tools are gaining increased acceptance for certain hazard endpoints (*e.g.*, mutagenicity, skin sensitization), others are less well studied and under active development (*e.g.*, developmental or reproductive effects).

Read-across approaches may provide additional information for establishing appropriate safety limits for extractable compounds lacking data. Recent regulatory guidance suggests that, for industrial chemical registration purposes, full chemical characterization and metabolic studies are required to demonstrate the suitability of a read-across approach. However, such a detailed approach may not be necessary when evaluating risks from medical device extractables present at significantly lower levels (resulting in relatively low exposure concentrations). Still, a robust read-across assessment should evaluate target and source compounds for reactive functional groups, structural similarity (*e.g.*, Tanimoto coefficient), structure activity relationship analyses, physicochemical properties relevant to hazard endpoints of concern, as well as specific structure-based properties or chemical behaviors (*e.g.*, redox properties).

Recent revisions to international guidance (*e.g.*, ISO 10993-1) and significant regulatory changes (*e.g.*, the European Union Medical Devices Regulation) have increased requirements for characterizing medical devices for potential chemical exposures and any resulting health risks to patients. Characterizing potential chemical exposures under exaggerated physiological conditions and evaluating potential risks to patients can fulfill these regulatory requirements, sometimes obviating the need for costly and time-intensive animal testing. While data gaps will always exist in such assessments, it is evident that predictive toxicology approaches will continue to develop as indispensable tools for addressing uncertainty and evaluating medical device safety.

The authors can be reached at jcohen@gradientcorp.com and mlewis@gradientcorp.com.

Do you have a scientific topic that you would like Gradient to write about in Trends? Send us your ideas for future Trends topics: trends@gradientcorp.com.

What's New at Gradient

Awards and Announcements

Joel Cohen has been appointed Secretary of the Society of Toxicology's Computational Toxicology Specialty Section.

Grace Greenberg has earned the qualification of Board Certified Environmental Scientist.

Publications

Callura, J.C., K.M. Perkins, J.P. Baltrus, N.R. Washburn, D.A. Dzombak, A.K. Karamalidis. 2019. Adsorption kinetics, thermodynamics, and isotherm studies for functionalized lanthanide-chelating resins. *Journal of Colloid and Interface Science.* 557: 464-477. doi:10.1016/j.jcis.2019.08.097.

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Long, C.M., P.A. Valberg. 2019. Low-Frequency Magnetic Fields: Potential Environmental Health Impacts. *Ency. of Envi. Health, 2nd Edition, Vol. 4* (Ed: Nriagu, J.). Elsevier, pp. 139–149.

Valberg, P.A., C.M. Long, L.A. Beyer. 2019. Toxicology of Ambient-air Particulate Matter (PM). Chapter 25. *Toxicology Principles for the Industrial Hygienist, 2nd Edition* (Ed: Luttrell, W.E., K.R. Still, J.A. Church, L.A. Beyer.). American Industrial Hygiene Association (AIHA), pp. 343-364.

Wait, D., T. Verslycke. 2019. Expert insight: Uniform data quality ecotoxicity assessment. *Natural Resource Damages: A Guide to Litigating and Resolving NRD Cases* (Israel, B.D., B. Marston, L. Daniel). American Bar Association, pp. 213-215.

Upcoming Presentations

Snowmass Village, CO. January 29, 2020. ABA Environmental & Energy, Mass Torts, and Products Liability Litigation Committees' Joint Regional CLE Meeting.

- **"Potential Health Risks & Regulatory Hurdles Associated with Cannabis & Its Concentrates."** J. Rice.

Seattle, WA. February 13-16, 2020. American Association for the Advancement of Science Annual Meeting.

- **"Updating the Delaney Clause: Mode of Action Considerations for Carcinogens."** B. Beck.

Anaheim, CA. March 15-20, 2020. SOT 59th Annual Meeting.

- **"A Comparison of PFAS Serum Concentrations in the General Population to Points of Departure Used in Regulatory Guidance."** S. Boomhower, L. Kerper, J. Chien, B. Beck.
- **"A Systematic Review and Analysis of Personal and Ambient PM2.5 Measurements: Implications for Epidemiology Studies."** S. Boomhower, J. Goodman, W. Li, C. Long.
- **"Risk Assessment of 1,1,1-Trifluoroethane (HFA-143a) as a Potential Impurity in HFA-134a in Metered Dose Inhaler Products."** R. Chang, I. Mohar, T. Lewandowski.
- **"Predictive Toxicology Approaches for Medical Device Biocompatibility Assessment."** J. Cohen.
- **"Defining the Edge: A Case Study in Expert Review of In Silico Hazard Predictions to Identify Activity Cliffs and Improve Chemical Risk Assessment."** B. Hansen, C. Marsh, J. Cohen.
- **"Known Unknowns: Challenges and Approaches for Handling Chemical, Hazard and Regulatory Uncertainty in Medical Device Safety Assessments."** Session chaired by T. Lewandowski.
- **"A Toxicologist's Primer on Alternatives Assessments for Green Product Design."** Exhibitor-hosted session. T. Lewandowski, J. Cohen.
- **"Systematic Review of the Potential Respiratory Carcinogenicity of Metallic Nickel in Humans."** R. Prueitt, W. Li, R. Chang, J. Goodman.
- **"A Comparison of Environmental Assessment Requirements of New Human Drugs in the U.S. and the EU."** I. Mohar, T. Lunsman, T. Verslycke.

Beneficial Use Assessment of Building Materials Containing CCPs

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Using this conservative approach, we demonstrated that there were no unacceptable risks to human health or the environment associated with the use of CCPs in siding materials. The same approach can be used to assess potential risks associated with CCPs in other products as well as for chemical constituents in other recycled building materials.

The authors can be reached at abittner@gradientcorp.com and alewis@gradientcorp.com.

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U.S. EPA. 2015. Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals From Electric Utilities (Final rule). Fed. Reg. 80(74):21302-21501. 40 CFR 257; 40 CFR 261. April 17.

U.S. EPA. 2016. Methodology for Evaluating Beneficial Uses of Industrial Non-Hazardous Secondary Materials. Office of Land and Emergency Management, Office of Resource Conservation and Recovery. EPA 530-R-16-011. 15p. April.

Guest Editorial: Assessing NORM in Australia

By Craig Heidrich

As concerns over naturally occurring radioactive materials (NORM) in coal combustion products persist, Australia has tackled the issue head-on with promising results.

Naturally occurring radioactive materials (NORM) are ubiquitous in the environment, being widespread in sands, clays, soils, rocks, many ores and minerals, commodities, products, by-products, recycled residues, and devices used or processed by humans. Although NORM are present in all naturally occurring substances (used by humans), the literature consensus is, where materials are extracted from the earth and processed, refined or combusted, NORM can potentially be concentrated in products, by-products, or waste (residue) streams. In particular, international concerns have been raised regarding NORM in coal combustion products (CCPs), which are the mineral by-products from the combustion of thermal coal to produce electricity, and in wastewater by-products of shale gas drilling and hydraulic fracturing.

Internationally, considerable attention has focused on determining appropriate safe exemption thresholds, along with management guidelines and regulations, for clearance of NORM.

Within a circular economy, by-products are increasingly used to manufacture value-added products, *e.g.*, construction materials containing CCPs, resulting in potential NORM exposures for both workers and members of the public. Internationally, considerable attention has focused on determining appropriate safe exemption thresholds, along with management guidelines and regulations, for clearance of NORM. The International Atomic Energy Agency (IAEA, 2004) has recommended an exemption threshold of 1 becquerel per gram (bq/g) for virgin materials (*e.g.*, sands, clays, soils, rocks, and many ores and minerals) as well as commodities, products, by-products, recycled residues, and commercial devices. Prompted by international thresholds, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) developed a nationally consistent regulation, coupled with methods of management across all jurisdictions of Australia.

One potential consequence of the ARPANSA regulation was the re-classification of CCPs for the purposes of NORM regulation and management, which carried with it serious implications for established-end use markets and potential new applications. Regulators recommended a substantial program to update and verify the NORM characteristics of current CCPs in Australia. In response to this changing regulatory climate, the Ash Development Association of Australia (ADAA) commissioned an independent study with the objectives of: (1) determining radionuclides present in CCPs (including for ultra-fine size fractions <10 microns in size), (2) determining any consistencies/inconsistencies with previous studies, and (3) conducting a comparison with existing natural materials and background Australian soil levels.

The results of this study (McOrist and Brown, 2009) showed that none of the CCPs analyzed would be considered radioactive from a regulatory perspective, as no single sample tested was above the international exemption limit of 1 bq/g. Furthermore, for applications where CCPs were blended for use, *e.g.*, for concrete manufacture, the contribution of fly ash to the total gamma ray dose from the concrete was found to be negligible. In summary, key study findings included:

- the low radionuclide levels present in CCPs (including ultra-fine fractions) are well below international and Australian adopted thresholds and exempt for the purposes of regulation;
- results are consistent with previous studies, therefore demonstrating the long-term consistent nature of CCPs; and
- the comparison with Australian background soil levels showed no significant difference to natural soils.

References:

IAEA. 2004. Safety Guide No. RS-G-1.7, Table 1, Application of the Concepts of Exclusion, Exemption and Clearance.

McOrist, G., S. Brown. 2009. Assessment of Naturally Occurring Radionuclides in Australian Coal Combustion Products (CCPs). Lucas Heights, NSW, Australian Nuclear Science and Technology Organization: Minerals, pp. 27.

Craig Heidrich is the Managing Director of HBM Group, a professional industry association management services company based in Australia leading the charge towards the effective utilization of industry by-products and recoverable mineral resources. The company specializes in strategic management, industry advocacy, RD&D management, policy development and membership support. This article is adapted from a technical paper.

Gradient
Boston, MA
Seattle, WA
Charlottesville, VA
trends@gradientcorp.com
www.gradientcorp.com

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