Operational Risk and Regulatory Compliance

A Guide for Site Managers in Midsize Organizations

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By Bertrand Kornfeld

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About the Author

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Bertrand Kornfeld co-founded and leads PDCAply, a start-up on a mission to provide site managers continuity in compliance through mobile services (SaaS) and technical assistance, consulting and application software distribution. Bertrand holds a BBA from HEC Montréal (1983) and a Theseus/EDHEC MBA (1990). In his early career with Hewlett-Packard and F. Hoffmann-La Roche AG, Bertrand managed fixed price IT projects and worked in the improvement of the heavily regulated drug development process in France, Switzerland and USA. From 1995 Bertrand consulted clients mostly as a freelance consultant but also for software publishers and system integrators in France, Germany, Switzerland and Finland. His clients include Novartis, Orion Pharmaceuticals, Siemens, the Swiss Federal Government and others.

Bertrand is a proven expert at realizing the benefits of proposition innovation to clients bearing legal liability in customer-related and professional risk management. He has been interviewed in La Tribune on delegation of authority and contributes regulatory experience to writing position papers for Syntec Numérique (a French professional association of consulting firms, system integrators, and engineering firms) on topics such as dematerialization, remote work, green data centres, business process optimization, as well as on the eco-design of ICT products and services.

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Your work, as an executive, is to run a site. You may be responsible for the profits and losses incurred. You may derive this responsibility either as a result of being the site manager, or as a result of having certain authority delegated to you by a site manager. Ultimately, you are responsible for the site's operations.

The success of your site does not rest simply on regulatory compliance. Your site's performance is probably metered against quantified indicators related to quality, lead times, service levels, volumes, and costs. Some believe regulatory compliance is a "cost of being in business," bearing little relevance to site performance. This report aims to offer additional insight on regulatory compliance and its importance to your site.

In the country where your site is located, your freedom to contract is burdened with obligations in relevant regulations:

- In order to be enforceable in a court of law, contract conditions must not force a party to violate a given regulation.
- Specific criteria in certain regulations, such as prohibited operations or products, may target sites of a particular type.
- The results that regulations may require can make contracts less workable.

Unless your site is a law firm or a provider of regulatory information services to law firms, tracking the advent of laws from all sources is tiresome and not at the core of your business. Most likely, you will only need an up-to-date synthesis of the current points of compliance your site has to meet. This list, with all of your compliance points, is called regulatory intelligence.

Other compliance issues are added to the regulatory issues by specialists on your site. You are the last gatekeeper of consistency among obligations. Assuming that you do not wish to create conflicting obligations on your site, it is important that you spend time checking your site for adherence to all obligations. These include obligations that do not stem from a law source such as voluntary measures in your industry, internal rules of your site, contractual obligations, and accounting standards.

Obligations are the crux of compliance. In litigation, where your personal liability is at stake, it is not you as an individual who is judged (therefore statements of moral support such as arguing that you are a good boss or that you did as you would have done for your children, etc. has limited impact). The judgment is based on whether or not an obligation has been met.

Result obligations are the most demanding. The most effective control option to eliminate hazards should therefore be the first choice. Only if the costs of eliminating hazards would force your site out of business, should you consider less effective controls. The next best thing is to define best available practices within the financial constraints of your site. This forces you to constantly seek better tools in order to keep your analysis up to date.

Obligations of means are the most frequent in regulatory texts. Among the range of possible options to control hazards, the regulatory text usually mentions just one. This option is generally the least effective method to control hazards out of all of the possible options. The range of options includes (sorted from most effective and desirable to least effective and desirable):

- Eliminate
- Substitute
- Isolate
- Control with engineering barrier
- Control with administrative barrier
- Protect the end of chain

Hazards are a consequence of the operations at your site and can be anything that could negatively impact a worker or an installation, as well as anything preventing work form getting done. The potential operational risk is proportional to the severity and frequency of the hazard. The residual operational risk is the potential operational risk divided by controls.

Partitioning the layout plan of your site according to where and which hazard(s) prevail(s) creates zones and makes operational risk analysis easier. Not only will you have a systematic way of addressing hazards, but you will also have a baseline of your site that can be used by all technical assistance providers. Because controls to limit hazards are technical in nature, it is important to inventory hazards to avoid the use of outdated technology. Inventorying hazards also allows you to get good tips on best practices from peers, friends and other people you trust.

You should keep a cautious eye even when controls are in place. Using another control to create a closed loop is a good way to avoid completely relying on a single control. Using the “5-Why” technique and FMEA on hypothetical accidents will help you focus your control on causes.

Where complexity exists, you will need to use the appropriate techniques to create models that reflect this complexity. Some examples of common complex situations include: three or more hazards interplaying in a zone, international activities creating operational risks, or when it may take years or decades for a hazard to develop.

Disciplined work on hazards and on controls will equip your site with the operational risk management necessary for success.

As you approach these hazards, you have two choices. The first involves making risk management your primary means of maintaining compliance to obligations. Remember, the cost of being in business is a bit of a self-fulfilling prophecy. By integrating risk management within the framework of your policies, procedures and processes, you ensure that your site can fulfill all of the tasks required to reach its objectives.

The second choice is making the management system of your site risk-based. If you choose to make changes to your management system in an incremental way then, from the beginning, you can aim for a certification of your entire management system. Work health and safety concerns, as well as environmental management are management domains where an OHSAS 18001 and ISO 14001 certificate are well within reach. Adding quality and ISO 9001 certificates is not much additional work either since ISO 14001 and ISO 9001 have a lot in common. One system and one audit bring one certificate of compliance to three international norms.

On a personal level, you will find yourself rid of the stress that comes from ignorance, inaction, the threat of personal litigation, the inability to delegate, and from addressing moving issues again and again.

As the person responsible for the bottom line of your site, you will avoid costs, gain margin on incremental business, be a better decision maker for investments and make/buy decisions.

As a manager, you will be in a position to mobilize people beyond your management team. You will be able to triangulate information on operations, to “walk the walk” on talks you have made, to be more empathetic with workers on your site, to see obligations threatening the existence of your site as early as possible, to anticipate change such as restructuring and closing down activities, and to implement early voluntary measures to deter regulation or change your site so that it remains compliant to regulation.

Context of Regulatory Compliance

Regulation vs. Contracts

Your site will always be bound to comply with the regulations of the country where it is located. Your site, as a legal entity, and you, as the individual entrusted with the highest level of authority, are legally liable for negative as well as positive consequences stemming from site operations.

Your legal liability can lead you to litigation. Arguing in a court of law that, "you did not know the law" can and will bring you the worst legal penalties. The legal principle "Ignorance of the law is no excuse" and your role as the authoritative presence on site will be seen[1] by authorities as you being able to use the services of a law professional.

Besides regulation "inherited" from location, as soon as your site begins to operate, a number of contracts are signed between third parties and the site. Obligations stemming from regulation do not have the same characteristics as obligations stemming from contracts:

Distinction between regulations and contracts

	Regulation	Contract
Scope of coverage	Broad (this country)	Narrow (this contract)
Room for negotiation	None (unless corruption prevails)	Depends on competing alternatives
Origin of obligation	If site meets inclusion criteria in regulatory text	If obligation is explicitly in contract or made mandatory by profession of third party
Risk of downside	High (legal risk)	Can be capped in contract
Where penalties are decided	Decided in a court of law	Can be negotiated in contract
Penalties nature	Fine, jail, negative listing[2]	Money and others as stated in contract

In a nutshell, regulations oblige and contracts engage.

1 If authority has been delegated to you but money has not been available to fund lawyer fees, then this delegation will have no strength and the person who delegated you the responsibility will be held responsible.

2 A negative listing is a penalty preventing individuals from participating in a regulated business. For example in France, a person can loose their right to run a business. In the USA, a person can be listed as a denied party in a customs procedure or as a disqualified person in dealing with the IRS or as a person barred from the drug industry by the FDA.

Engagements made in a contract must[3] be legal in the country where litigation on the contract could occur. Getting applicability of contracts checked for what a judging authority will see when looking at the contract later is a minimal level of professionalism in making contracts.

The use of standard conditions in contracts is made mandatory by some regulations. Think of a work contract in an industry where collective bargaining has occurred.

If credible controls (for instance, exposure limits for nanomaterials in the workplace) or if resources for performing controls (available inspectors) do not exist, a regulatory text can, in the short-term, be ignored. In some cases, a particular obligation stemming from regulation may be safely ignored if another regulatory text explicitly makes compliance unnecessary. As always, it is best to confirm these situations with a law professional to make sure that you will remain within the law.

A great deal of diversity exists among countries in terms of what can be the object of a contract and what is prescribed by regulation. History, culture and values as well as the position of the economy on the continuum from "liberalism" (little regulations and lots of space for contracts) to "dirigisme" (lots of regulation constraining what can be contracted) contribute to framing the context of regulatory compliance and to sizing public ownership of firms.

China and France, despite their many social and political differences, can be noted as two countries where dirigisme prevails in the economy.

Long periods of dirigisme in an economy result in numerous layers of regulation. Rarely does a legislator have an appreciation of the entire set of regulatory obligations of a particular site. Moreover, few legislators have diversified experience with running businesses, and they do not always agree with other legislators on the purpose of a regulation.

These government-owned monopolies are given many advantages when government owns capital in firms for long periods of time. Legislation proposed by governments tends to favour the interest of those firms. The history of countries where the economy is skewed towards dirigisme leaves entire industries under the control of state-owned organizations. Similar industries in countries where the economy is skewed towards liberalism are made of firms owned by private shareholders.

An example of such industries is basic health insurance services that are obtained from a number of insurers in Switzerland and from a single state-owned provider in France.

As a last note on source, contract obligations are not only found in commercial activities when negotiating with clients. While performing daily activities, you are also involved in closing contracts for many of the decisions that you are making. Purchasing, hiring, building, transporting, renting, and sub-contracting decisions entail obligations stemming from contracts.

3 If a contract violates a regulatory obligation of one of the signing parties, this contract will hardly be enforceable in a court of law.

A contract that would force a party to violate regulation could be nullified in a court of law. The habit of copying and pasting the previous contract and just changing the third party and date text increases the risk of nullification, especially in the face of constantly changing regulations.

As a conclusion, obligations of both contracts and regulation need to be fulfilled; bearing in mind regulation takes precedence over contracts. Identifying precisely which terms of a standard contract derive from which regulatory limitation is one of the best means to make contracts as simple as they can be and thereby effective in a contract litigation.

This brings us to the creation of regulatory texts.

Sources of Regulatory Texts

A corollary to the "ignorance of the law is no excuse" principle is that regulatory texts materializing the law should be accessible to all. Almost 20 years after HTML was defined, a vast number of websites are now able to access regulatory texts.[4]

The abundance of sources and the easy access does not seem to have made knowledge of regulatory obligations more usable in daily work however.

National Laws

Depending on political systems, laws are most often voted on by representatives who are elected by people. Depending on legal systems and content, a law that is voted becomes immediately applicable, has an application date in the future, or has to await regulatory measures to become applicable.

National law is, in all but rare city-states like Singapore, a combination of regulatory texts from all sources. In most cases, sources of national law include:

- Country or federal
- Land, province, region or state
- City

Countries where dirigisme prevails have added or let survive additional layers of legislators.

Supranational Laws

International Agreements, Protocols and Free Trade Zones

Supranational laws include international agreements among countries (such as the ones under the United Nations), protocols when countries have been unable to ratify agreements due to internal opposition and free trade agreements.

Examples include the United Nations Convention on the Rights of the Child and the additional protocols of 2000, 2002 and 2011.

4 36,900,000 hits were found looking "Sources of regulatory texts" on October 11, 2012

Free trade zones are created by treaty. Examples include the North American Free Trade Agreement (NAFTA), the Mercado Común del Sur (MERCOSUR), the ASEAN Free Trade Area (AFTA) and the African Free Trade Zone (AFTZ).

A Case with More Constraints – The European Union

As of early 2013, 27 countries in Europe belong to the European Union. The European Union is a source of regulatory texts.

A European directive has to be transposed into national law within a defined timeframe and with associated fines for defaulting. A European regulation is directly applicable in all countries of the European Union, similar to a federal law in the USA.

A typical example of European regulation is REACh (Registration, Evaluation, Authorisation, and Restriction of Chemicals). With the goal "to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry,"[5] this ambitious regulatory text impacts firms that not only produce chemicals, but also use chemicals, distribute chemicals, and import or export from the EU. A European Agency (ECHA) pilots REACh implementation. Additionally, national authorities control implementation in each EU country.

Jurisprudence

Besides national and supranational laws, legal decisions made in the last jurisdiction handling appeal of lower level jurisdictions create an additional source of law. Decision makers define in a particular case how the obligations set in the law apply. All similar cases must from then on take into account the decision.

In an ideal world, a regulatory obligation should appear in one and only one text. In practice, and especially where supranational laws exist, a given obligation can appear in multiple laws. For example, obligations exist in regards to CMR[6] substances in the workplace in the laws of many countries, but they also exist in REACh. As a principle, compliance with the most stringent obligation should assure compliance to all obligations. Relocation of a site, if feasible, might be an alternative to compliance in some situations.

Quasi-Regulation

Voluntary Measures

Voluntary measures are decisions made by a group of firms (usually in the same industry) to adopt a given obligation. These self-decided obligations can embody best available techniques and keep compliance costs within what the industry can bear. Other industries unable to devise voluntary measures of their own might end up being regulated. These voluntary measures are one way to avoid governmental regulations that may negatively affect firms.

5 http://www.echa.europa.eu/web/guest/regulations/reach/understanding-reach

6 Carcinogenic, mutagenic or toxic for reproduction

Internal Rules

Internal rules exist on your site. The written part of these rules can and should be used for compliance purposes. Irrespective of what you call them (internal rules, rules of procedure, code of conduct, etc.), these written materials should explicitly describe non-job-specific responsibilities of each and every worker (including yourself) at your site. A good test of your internal rules should consist of checking for the following guidelines:

- Modern technology guidelines (data privacy and e-mail? the use of social networks on the job?)
- Application of principles you use when you recruit (are words you use to describe your site as an employer reliably translated into obligations in your internal rule?)
- Personal interactions to prevent potential problems for individual workers (harassment, etc.).

Contractual Obligation

Whenever entering into a contract you should assess the feasibility of every contract obligation against legal obligations, voluntary measures and internal rule. Failure to do so is asking for trouble.

Accounting Standards

If the financial accounts of your site undergo auditing against international accounting standards, auditors will assess your operational risks and calculate accordingly the amounts that you need to provision. As provisions are liabilities, sizing them incorrectly could adversely impact your bottom line.

What Does Personal Legal Liability Mean?

Being personally liable for an obligation means appearing before a court of law where other non-compliant individuals are being prosecuted. To put it more bluntly, any fines would be paid with your own money (not the company's money or its insurance) and you would serve any jail time should that be what the court decides. You would also lose your right to perform some business activities, should your name be added to a negative list.

Depending on laws prevailing in your country, obligations set in regulatory texts are mostly obligations of means. For instance, if a dangerous substance must be manipulated during work, then the obligation to label the substance to inform workers (means of information) and the obligation to provide protective equipment (means of protection) are mandatory.

In some countries, notwithstanding obligations of means, there are obligations of results set in laws. For instance in France, a site manager (known as the *employeur*) has a general result obligation for safety at work set in work law. Sub-contracting the manipulation of a dangerous substance on the site does not transfer the responsibility because the result obligation includes all humans in the workplace regardless of the contract nature that brought them to be on-site.

If your site is larger than a single open space where everything is visible at a glance, then you probably have organized work along the lines of an organizational chart. Empowered managers can and should be made responsible for operational risks among people they manage and for the premises they use.

As a conclusion on regulatory compliance, sources of obligations are diverse and some of them are under your control. Making what is necessary to abide by the "ignorance of the law is no excuse" principle on your site is a process. This process starts with a list of obligations at a given date. The process lives with new regulation and jurisprudence, as well as changes occurring on your site.

Very much like quality, the compliance process cannot be done after the regular work of your site, nor can it be outsourced. It has to be realized with resources available to you. Furthermore, process failures in regulatory compliance do physically impact these very resources.

Existing Resources to Manage Operational Risks

The human resources available to you to manage operational risks at your site are people able to provide you with technical assistance. They are either employees of your site, staff managers at the headquarters of your company, or professionals with whom you contract.

The way work is performed in practice at your site is your key resource. You need to make sure that this is documented in a format that is usable by all of your technical assistance providers. This will help to minimize out-of-pocket costs for technical assistance services (as technical assistance provider's learning curves will be steep) and will possibly make their work more beneficial for your site. A useful way to view inputs to management activities and the risks that occur with uncertain information is illustrated in the diagram below:

Sorting out operational risks from enterprise risks

Operational risks are risks attributed to work performed on your site in order to deliver products or services. If your site is the only one in your organization then you also manage risks associated to R&D, strategy, and finance.

Risks unrelated to work performed to deliver a product or a service is often included in enterprise risks.

To further illustrate the difference between operational and enterprise risks, let us imagine a site delivering a product facing one of the following adverse situations:

- Product is not sold in a market where explosive growth is occurring
- Product technology is obsolete
- Product is counterfeited on a wide scale

To sort out operational risks, one should look at the answer to whether or not actions taken on-site can change something in the situation. If the answer is yes, then it is most likely an operational risk.

Your Work Practices

The sheer fact that your site is and remains in operation demonstrates existing work practices that allow you to achieve your site objectives.

Work practices at your site are the result of history, of resources available to workers, of worker skills and headcount, of methods and tools used to perform work, of work climate, of performance evaluation and of management proximity with work being performed.

Even if you are fatigued by heavy usage of the term "process", your work practices should describe processes as they are executed by workers because operational risks stem from site operations.

Unlike other process descriptions serving a unique purpose, description of work practices for operational risk management combine human, technology and organizational attributes as a set of interrelated elements (in a systemic manner). Artifacts from these elements surround employees or are created by employees (NB: Managers, including yourself, are considered in this report as employees).

Artifacts surrounding workers may include: facilities, tools and equipment; instructions and training to use equipment or an IT application; job description; organizational chart; process description; and standard operating procedure.

Artifacts created by workers may include: adaptation to exceptions (workarounds, *tour de main*), norms to recognize professionalism and reactions to work or load characteristics (stress, conflicts, etc.). We will focus on technology used to describe work practices later in this report.

These artifacts are stimuli your workers use to create perceptions about their work environment. You will foster positive perceptions of work practices at your site if no void exists and if these artifacts make sense. Conversely, chaotic and incomplete artifacts are stimuli leading to less positive perceptions.

Technical Assistance on Regulatory Compliance

Technical assistance is specialist knowledge applied by a professional to narrow topics. These specialists also have a depth of understanding in relation to recognized site practices. Because risk management is increasingly an obligation in regulatory texts, skills needed from regulatory compliance experts are changing accordingly.

Functional Managers

Staff managers at your site or at the headquarters of your company, regardless of their title, can be instrumental if they agree to assist you practically in handling the issues at hand on your site. Those wishing to stay at the level of principles or who are only ready to tell you what to do should be avoided for a second call.

Specialties of functional managers are shown by types of operational issues in a retail, research, manufacturing or healthcare and residential care site:

Specialities of functional managers

Specialty	Goal or Skills	Site managers typically expect the following assistance related to operational risk management
Ergonomics	Adapt work to humans	Improve work conditions factoring in both objective and subjective physiological, psychological and social aspects
Human Resources	Deal collectively with workers	Keep internal rules up-to-date, ensure compliance to labour and social laws as well as perform work relations
Industrial Hygiene	Physicians and engineers	Anticipate, recognize, assess and control health risks in a work environment
Information Technology	Deliver useful applications	Create operational plans, track execution of work and perform regulatory requirements (e.g. label chemicals)
Process Management	Build safety into work processes	Manage change towards usage of protection means
Regulatory Intelligence	Anticipate regulation	Elucidate and keep current regulatory compliance requirements as well as propose voluntary measures

Specialty	Goal or Skills	Site managers typically expect the following assistance related to operational risk management
Hazard Specialists	Chemicals	Use MSDS data to establish bills of substances and develop exposure scenarios
	Dangerous goods transportation	Assure dangerous goods leaving your site follow requirements of transportation means used
	Environment	ISO 14001 environmental management system, carbon accounting, relationships with site neighborhood
	Explosion	Zoning of premises, intrinsic security, engineering barriers, access control to explosive atmospheres
	Fire	Fire permitting, fire prevention, relationships with fire emergency people
	Noise	Identify work places with noise issues and devise means to bring its level under painful and harming levels
	Process failures	Lean management, statistical process control, asset management if automation
	Radiations	Visualisation of zones containing radiation emitting equipment, inventory of nuclear products and waste
	Transportation	Implement measures to control risks associated with transportation both on-site and on roads
	Vibrations	Identify work places with vibration issues and devise ways to bring its level under painful and harming levels
	Waste	Classification of waste, waste disposal technology and control over physical flows of waste

Law, Medical, Engineering, Consulting, Insurance, and Accounting Professionals

Many professionals you have already contracted may be knowledgeable about your site operations and their expertise might therefore be helpful in developing operational risk management protocol.

An obvious mapping of professionals to types of operational issues is:

- Engineers to scientific and technical issues (dangerous machines, protective barriers, facilities design, automation, etc.)
- Lawyers to regulatory and litigation issues

- Work physician to at-work health issues

Holders of these skills can be employees or suppliers. Savvy suppliers embed those skills to augment their core product, are mandated to do it by regulation or are consultants.

Another set of resources with a less direct intervention on operational issues may include:

- Accountants who have to assess your operational risk to calculate or audit the money set aside (provision) to cope with consequences of accidents
- Consultants who may have privileged knowledge of your operations from previous work or be instrumental in minimizing the distance between work as you perceive it to be done and actual practice; as well as be actors in managing change
- Insurers of your site who have to calibrate the premium you pay to the moral hazard associated with your operations (moral hazard in this context can be seen as assessing what you do to prevent accidents at your site)

Mandatory Employee Groups Addressing Health and Safety Issues

Depending on regulation in your country, you may have an obligation to organize elections among workers and sometimes directly manage a group of workers dealing with health or safety at work. Besides freeing them from regular work during group activities, you may have to provide them with training and pay for any technical assistance that they may need.

For instance in France, from the 50th worker on a site (250th in the public sector), a site manager has to lead a *Comité d'Hygiène, de Santé et des Conditions de Travail* (CHSCT).[7] Presenting once a year, in a consolidated document, the site's operational risks is an obligation.

On sites where major hazards and a responsible manager for safety exist, responsibility for that obligation and associated legal liability might be delegated by a site manager to the head of safety.

7 Committee for hygiene, health and work conditions

What You Need to Know and Can Do

Even if, as is often the case in management activities, the devil hides in details, there are two fundamental notions where precision and specificity of vocabulary really bring clarity.

What is a Hazard?

A hazard is anything stemming from your site operations that could wound/kill a worker of your site, deteriorate/destroy your facilities or slow down/stop work at your site. A hazard causes incidents (small impact) and accidents (big impact).

Examples of hazards and accidents include:

- A substance present at work will intoxicate workers or irritate their skin
- Dust will cause an explosion that kills people and deteriorates buildings
- Import difficulties on a vital input will stop assembly because of subassembly shortage
- A machine breakdown will wound a worker and slow down work
- A natural event strikes your facility and makes your site unfit for work (a flood in a shopping mall, an outbreak of legionnaire disease at a healthcare and residential care site, a lightning strike at a factory, an earthquake in a high rise office building, etc.)

Some hazards have immediate and dramatic consequences, for instance an explosion or a fire. Others involving diseases may take time, up to decades, before consequences become visible.

What is an Operational Risk?

An operational risk can be seen in a first approximation as the likelihood (probability) a hazard will materialize into an accident at your site.

Unlike in investment strategies where some risk appetite is beneficial (returns are commensurate to risks), no operational risk is desirable in these cases. There is no one who will benefit if more risks are taken in operations.

This being said, the only way you can bring the vulnerability to zero is to completely stop operations at your site. To further qualify operational risks, additional indicators such as severity of accidents and frequency of operations bring light to risk assessment. A hazard with high severity (involving death of workers and catastrophic destruction for your site) should be addressed, even if the likeliness of the occurrence is very small. A small impact hazard in operations that are repeated a large number of times should also be addressed.

Being a little bit more analytical, one can say that the potential operational risk (operational risk with no controls) is the product of Hazard times Severity times Frequency:

Potential operational risk =
Hazard × Severity × Frequency

Control measures of hazards (controls) can be devised to decrease the probability of accidents. Some regulatory obligations are prescriptive in this regard.

Looking from an analytical lens once again, one can say that the residual operational risk after controls have been implemented (and assuming controls are failsafe) is the fraction of potential operational risk divided by controls:

Residual operational risk =
Potential operational risk ÷ Controls

In designing controls, a number of options exist to decrease the odds of an accident. The following control options are available to mitigate risks:

- Eliminate
- Substitute
- Isolate
- Control with technical (engineering) barrier
- Control with human (administrative) barrier
- Protect the end of chain

These options are sorted from preferable/most effective to less preferable/least effective and options can and should be combined for the sake of reliability.

The following are examples of risk mitigation[8] on a research site, for a process manufacturer and for a discrete manufacturer.

8 Risk mitigation is the function performed by a control

Risk mitigation options for research, process and discrete manufacturing sites

		Site operation and hazard		
		Benzene used as solvent on a research site	Storage of grain flour on a site processsing food	Essential components from Japan assembled in electronic board subassembly in China on an aerospace & defence manufacturing site
		Benzene is a carcinogenic and explosible substance	Dust causes an explosive atmosphere	Political tension between China and Japan
Control options	Eliminate	Externalise operations with solvents (transfer risk) or use no solvent process	Do not keep flour in inventory	Do not import essential subassembly of one's products
	Substitute	Use Toluene instead, albeit neurotoxic, it is not carcinogenic	Store next step(s) in the use chain of flour thereby eliminating dust	Have a second source for assembly besides China
	Isolate	Enclose use of solvents in an hermetically sealed environment	Store flour in in a remote or a bunker-type of silo and use through continuous pipe from silo to machine	Know the impact of geopolitical evolution on your supply chain and diversify sourcing
	Control with technical (engineering) barrier	Use under hood or with local exhaust ventilation	Make silo hermetic to air and inert dust with nitrogen	Degraded functioning of product with board functions made by software until subassembly becomes available
	Control with human (administrative) barrier	Four eyes principle when using solvent, compliant labelling and storage	ATEX (OSHA NFPA in USA) compliance (zoning and equipment), as welll as cleaning and control of maintenance	Import components from Japan and re-export them to China
	Protect end of chain	Use supplied-air repirator and wear chemical resistant gloves, coveralls, boots, and/or other resistant protective clothing	Nobody working within explosion range from silo	Keep appropriate safety stocks of subassembly

How to use Regulation to Minimize Your Compliance Burden?

Regulatory obligations will in very few cases be a result obligation. Most often regulation will mandate one of the control options as means of compliance.

Result Obligations

A result obligation is the most exacting to comply with. Using the most effective operational risk mitigation is what you should aim for in a first step. Analyzing the state-of-the-art and getting offers from leading suppliers will provide a glimpse of the costs for fulfilling this result obligation. Suppose you are using a chemical substance whose risks have been evaluated for REACh and deemed too high to be granted an Authorisation and being therefore subject to a Restriction. This means this substance can no longer be manufactured, imported, sold or used in the EU. Your alternative is to replace the substance by one or more authorized substances, requiring process and product R&D, or to relocate the process using the restricted substance to a country where REACh does not apply. If this substance is purchased, it is likely that your suppliers will have performed R&D to offer alternative substances and keep their revenue stream.

You should only look at less desirable options if there is not a viable solution in the state-of-the-art. If the only available solution using the state-of-the-art incurs excessive cost (e.g. compliance would force the site out of business), then it will be necessary to look elsewhere.

Selecting anything other than the most effective option will force you to frequently update your analysis, so that your logic is based on current data ("frequently" is to be understood here as at least once a year)

Your logic should be understandable to decision makers in a court of law if you want to help your attorneys dealing with litigation on a result obligation.

Means Obligations

Regulatory obligation of means prescribe the use of one of the control options.

You will possibly run a compliance project to meet your regulatory obligation. In the course of this project you will estimate costs of compliance. Before you calculate costs and, in any case, before committing resources, you should:

- Assess if the same resources could not eliminate hazards and exclude you from inclusion in sites having to comply to this very obligation
- Consider combining options within the same effort and budget to create closed loop controls

Gaining Adherence to Individual Protective Equipment

The "protect end of chain" option sometimes forces workers into a situation where they perceive a decreased level of work effectiveness when using individual protective equipment (IPEs: hard hats, hearing and eye protection, etc.). Irrespective of how much training and information you

provide, workers might elicit not to use IPEs. Adding usage of IPEs in your internal rule, albeit a good idea, might not suffice to ensure widespread use of IPEs.

One of the very few ways to influence adherence is to involve key people in designing IPEs. In every work environment, norms of professionalism exist and individuals enjoy authority of competence. If and when the worker acknowledged by peer workers to be the most professional, starts using an IPE, most other workers will adopt the IPE designed and used by their role model over a period of time. Granting autonomy and authority to an individual outside of your management team might prove to be the safest way to IPE regulatory compliance.

Your task will be to control egos of professionals and individuals in your management team so that they do not prevent, even involuntarily, change from happening.

When to Use Which Technical Assistance?

Using technical assistance will, in most cases, be needed to dig into means of compliance. Believing that only money matters in getting useful technical assistance is an error. Of course if money is no object on your site, contracting with the best professionals is a great way to ensure value.

Your peers and managers of sites similar to yours in other states/regions/countries/organizations, can be helpful resources if you have done your homework in terms of understanding inclusion and exclusion criteria for sites and associated obligations as they are stated in regulatory texts. Eliciting regulatory compliance tips and good practices without homework resembles bad manners and will bring you little in most cultures.

To perform homework, you could contract professionals or use soon-to-be-professionals. A finishing student in an engineering school can within a few weeks provide you with a sound analysis of which site characteristics meet inclusion criteria of a site in a regulatory text and of corresponding obligations.

From experience at retaining professionals and occasionally at using the result of their work in operational risk management, I recommend avoiding the following traits, which most of the time give what I believe to be sound reasons for not retaining a professional.

Reasons to not retain a risk management professional

Trait	Reason for not retaining
Uses the words risk and hazard interchangeably	Confusing, possibly "wafflers"
Are experts of a hazard but know little about how and when a hazard will cause an accident, ignoring that the hazard might interact with other hazards	Deep scientific and technical hazard knowledge hampers more mundane analyzes of accidents
Produces description of operations with tools where a hazard cannot be modeled/drawn, let alone be associated to an occurrence probability	Uses tools inappropriately to issues at hand
Spreads the very same best practice to comply to an obligation wherever they intervene	Will seek once more to implement their solution looking for a problem

Addressing Bathtub Issues

Poorly designed controls tend to be unreliable, to favor transferring issues as opposed to addressing issues and are hard to integrate with existing resources and technology.

Reliability of Controls

Some of you who may, like me, thoroughly enjoy driving a premium, four-wheel drive vehicle, know that the extra road handling abilities bring a sense of confidence that sometimes translates in higher speeds where and when speed controls are not present. We should also be aware that the slightest electronic glitch could transform the vehicle into automotive waste.

Controls you implement can generate hazards if you trust them blindly just like the driving of a four-wheel drive vehicle. The sheer existence of a control gives you a high sense of confidence that the hazard is controlled. The best way to ensure that the hazard is controlled is by implementing a control option to control reliability. If you have a control option in place that monitors your control reliability, you create a closed-loop control.

For instance, let's say that you have implemented a local exhaust ventilation (LEV) to control a dangerous substance found in the air on your site's premises. Then you also decide to implement a flow meter connected to an M2M device[9] that will send flow data as an SMS to the person responsible for safety, letting him or her know if the flow level falls below what the LEV should produce. This is a great way to create a closed-loop control.

The second control will cost you a tiny fraction of the first control, both in investment (hundreds vs. tens of thousands) and in running costs (hundreds vs. thousands).

Effective Problem Solving

Because operational risks stem from operations, addressing operational risk issues should be based on a model or description of work processes. A model is a relevant simplification of reality, which is good enough to understand a particular aspect of reality. Do not imagine model means complex, hard to understand or needing "modeling" application

9 A mobile phone that can only send short messages

software. I have seen talented people sketching very revealing models on simple flip chart pages.

Begin with an image of the whole. If you are analyzing the site, this could be a diagram of the layout of the entire site. Depending on the operational risk under analysis, you will mark the rooms/areas/floors/building onsite where the operational risk does not exist. Simply assuming that a risk only exists physically in the department where the risk-creating activity is being performed, is usually a bad rule. For instance, if there is a hazardous substance being handled on your site, you will most likely need to include the entire site including offices. Just because the hazardous material is not coming into direct contact with the office does not mean that it will never be present there. If offices share the same air as the area where the substance is handled, then your offices need to be included.

Unlike in the animal kingdom where dangerous animals tend to have flashy colors, a hazardous substance may have the same color and smell as water but be as toxic for those manipulating it as for those in nearby offices sharing the same air.

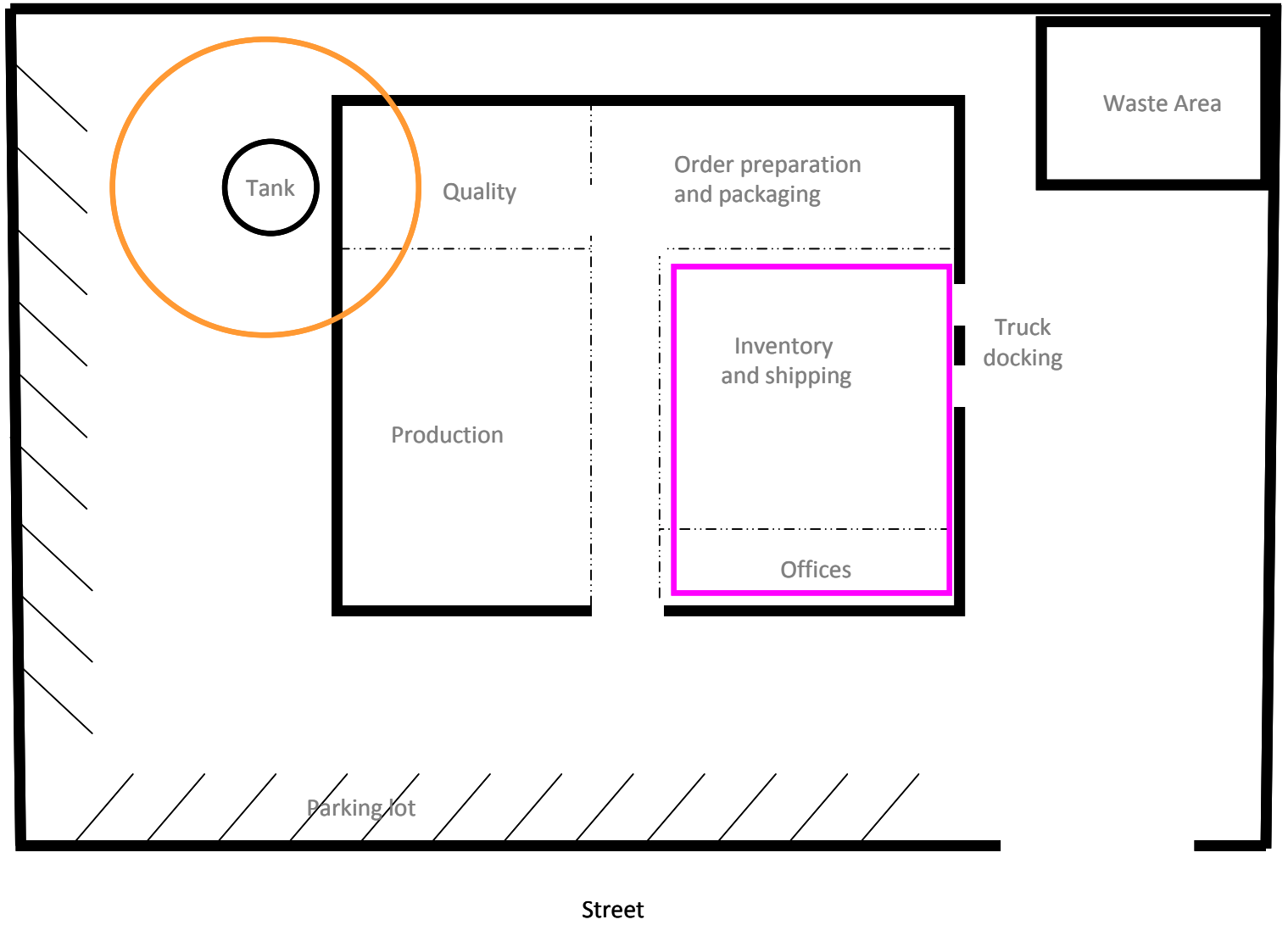
Zoning should be developed for each hazard. Zoning is a regulatory obligation if explosive atmospheres exist. Other examples of zoning include nuclear medicine regulation on a health care site.

To make zoning somehow more concrete, let us look at an example. We are on a manufacturing site. Quality control is made in a non-destructive manner and realized on 100% of production by means of an explosive gas stored in a tank located outside the building. On the same site a hazardous substance is re-packaged from large containers and packed into a sealed canister mounted in production on the machine using this substance. Air circulates freely between offices, the inventory and shipping department.

On the site's layout plan, you will need to show two zones that appear at once:

- A circular and orange zone where everything will be destroyed, should the tank explode
- A rectangular and pink zone covering offices, as well as inventory and shipping

Visually this simplified zoning is as follows:



Zoning your site to asses operational risks

Reviewing these zones quickly brings to light the following:

- **Orange zone**
  - Radius of circle is determined by quantity in tank
  - Having anything explosive within the zone creates a domino effect
  - No human should perform their work within the circle (eliminate target[10])
  - Savings generated by purchasing tank content in large quantities must be balanced against hazard generated
  - An even larger quantity could make the circle bigger and pass the property limit of your site. This would make your site a hazard to its neighborhood and possibly a site controlled for environmental protection.
  - Building an explosion resistant wall near the tank is a typical false good idea because a car parked there would create a domino effect
- **Pink zone**
  - The entire area where air is shared is impacted by the hazardous substance
  - Controls can be designed using the following options:
    - Eliminate: get sealed canisters to be filled by supplier of substance
    - Isolate: create a chemical storage area in the south-east quadrant of inventory and shipping that is isolated from other areas with an air circuit that is distinct from the pink zone
    - Technical barrier: ventilate from the outside creating slight vacuum

Before you apply the "one crisis one platoon" principle and route each operational risk to the most likely provider of technical assistance on controls, you should go the additional few miles of making sure you are looking at the entire picture and not just one component.

Reasoning on hypothetical accidents and applying the five whys method or other accident analysis tools you may be familiar with, such as failure modes and effects analysis (FMEA), will help you to clarify your expectations towards technical assistance.

If you can help providers of technical assistance quickly understand work at your site and have already performed the basic analyses, you might end up selecting a different provider of technical assistance and will in any case get more for your money. This is because as little time as possible will be needed to communicate your context to the provider of technical assistance.

10Another model linking hazard and operational risk that prevails in some regulatory texts imposing obligations in terms of safety improvement. In a nutshell the model states Operational risk = Hazard X Transfer X Target where transfer is the mechanism bringing the danger in contact of the target and the target is the human being submitted to the hazard. A safety improvement is either eliminating transfer or target.

Using Sensible Techniques for Compliance and Automating Activities

With perseverance of work on hazards, zones and productive technical assistance, you will eventually get a complete and consistent map of where each hazard might cause a specific accident.

For the hopefully few spots on your site where three or more hazards interact, you may have to use a more powerful modeling technique amenable to handling complexity. Systems thinking and its starting point, causal loop analysis, is a prime candidate for controlling interactions among multiple hazards.

On top of multiple hazard interactions, hazards stemming from international activities and hazards with asynchronous effects should also be analyzed by appropriate methods.

Even if incomplete, the map is a powerful yardstick to assess your plans. Detecting in your operational plans[11] the subset of work that increases risk will help you either marginally change your operational plan or apply special care on these exceptions.

For instance in a plant, think of the materials issued to serve two work orders when each material contains a substance that reacts strongly with the other. If these materials are physically issued in the morning, the two materials will be close to one another when work orders are soon to be served from inventory. Furthermore, materials might be transported together compounding the issue. Do bear in mind the list of substances, in anything bigger than minuscule amounts, is on the Material Safety Data Sheet provided by the supplier of this material. The same MSDS has indications of substances that react strongly on their own or when interacting with other substances.

Delaying one of the two work orders by one day is a marginal change to operational plans. This decision desynchronizes usage of the two substances and effectively mitigates the risk that the two substances will be in contact during inventory management or during transportation from inventory to point of use in production. These kind of controls are necessary in order to avoid risks.

A control is of a technical nature. Even before you came to think of implementing controls on your site, humans and the organization itself might have already started doing it. To foster success you should recognize risks being mitigated and then find out who has brought about this innovation to your site's work.

Celebrating success will not only be good for those involved, but it will also help you understand the kind of automation people value on your site. Going on the application software market for a solution to automate controls, even the SaaS[12] ones, may seem like a good idea, when in fact it could be damaging to your operations. Your site might

11 An operational plan in a plant is your production and transportation schedule. Hospital dosing plans (which drugs in which quantities have to be delivered to which patients in which rooms) and rare skill/rare technology schedules (surgery, scanner, etc.).

12 "Software as a Service" subscription in the cloud

use equipment with embedded controls. Getting your workers to switch on the control mechanims embedded in the equipment will most often cost less than even an aggressively priced SaaS.

Another reason for not selecting software is because many application software purchasing processes place an emphasis on requirements definitions. Purchase of software is seen as a large ticket item and as a commitment for many years to come. Due to that, users often express what they think they need now and what they anticipate to need in the future. As a consequence, many requirements definitions are laundry lists of requirements. Vendors enjoy long and detailed lists of requirements. The better providers will have a close to 100% yes rate on lists of requirements with no internal contradiction.

Key users might not be good at describing a function in a manner complete in the eyes of an IT professional, but will tell immediately when shown a function what is OK and KO and explain why. This essence of designing an information system should be done before looking for application software. The crudest means should be used for that purpose:

- To put together lists: spreadsheet
- To make calculation: spreadsheet
- To mock-up a user interface: drawing software or paper, scissors and pens

Once satisfied with a design, implement it on an electronic media device using whatever relevant information technology you understand (AJAX, Flash, HTML5, animation in a drawing application, other). If and when selecting software, you will have a small prototype of what you want.

However disgraceful the results produced by such code might be, you will more importantly, have a powerful transitional object to deal with presales engineers.[13] The most competent of presales engineers will enjoy not having to argue about answers to the requirements definition and will give you valuable technical assistance.

You will also have the baseline to plan elements for your site. Those who implemented existing controls are prime candidates to contribute further to what your organization gets.

13 Sometimes called presales consultant, it is a person whose services are a sales cost for a software vendor and who aims at solving software usage issues before application software is acquired.

What Your Organization Gets

The management system of your site is the framework of policies, procedures and processes used to ensure that your site can fulfill all tasks required to reach its objectives.

To reach site objectives your management system may implement a number of strategies, including process optimization, management focus and disciplined management thinking, as well as strategies specific to your organization, your culture or your industry.

To work effectively, a management system rests on the four legs of a shared vision of the site:

- How information is shared
- How performance is measured and made comparable with other organizations
- How teams work
- To which quality, health, safety and environmental principles your site subscribes

Your management system embodies the organization of your site.

Risk Management System

Having done the homework of locating hazards on your site, of assessing gravity and estimating frequency, you have started developing risk management.

Being there you are indeed at a crossroads:

- One way leads you towards keeping your operational risk knowledge for regulatory compliance purposes
- The other way leads you to integrate operational risk management into your management system

The first way makes the argument that regulatory compliance is just a cost of being in business, a self-fulfilling prophecy.

The second way leads you to enrich your management system with operational risk management practices. This will make regulatory compliance an outcome of running the management system.

Continuous Improvement

Continuous improvement is a mode of change located on the extreme incremental side of the incremental to radical continuum. This continuum can be seen as follows:

Incremental to radical continuum of improvement

	Incremental	Radical
Most widely used names	Continuous improvement Deming wheel Kaizen Plan-Do-Check-Act (PDCA)	Business process reengineering Business transformation Restructuring
Lead author	Edward Deming	Michael Hammer
Frequency of change	Often	As little as possible (traumatic)
Typical attitude towards workers	As benefactors of improvement workers need to understand and appropriate change	Workers must embrace new ways or face (Schumpeterian) creative destruction of their job
Typical attitude towards resistance to change	Understand in human, technical and organizational elements which ones interact towards resistance to change. Either change the improvement so that it becomes acceptable to workers or relax constraint on work.	More training Coercion against troublemakers
Typical functioning with hierarchy	Top – Bottom – Up	Top – Down

Continuous improvement is on the mind of almost every writer of standards on management systems. This is true of standards of management systems originating from ISO (International Organization for Standardization), from OSHA-EU (the European Agency for Safety and Health at Work), but also from OGC (British Office of Government Commerce) and ILO (International Labor Organization).

Compliance to management systems standards enables certification of your site. The actual level of excellence of your practices has nothing to see with certification. Your management systems will get certified if you have an auditable analysis of the situation and a continuous improvement plan, even if performance metrics of your site are abysmal.

If you have gone the way of managing operational risk, a certification of your management system to ISO 14001 (environment) and to OHSAS 18001 (health and safety), is well within reach. If an ISO 9001 (quality) management system is there, you can invite quality to the party because ISO 14001 and ISO 9001 have a lot in common. NB all of these standards are risk-based.

What I am discussing here is a single certificate stating the management system of your site is compliant to three standards. This is one continuous improvement effort, one audit and one certificate of compliance to three standards.

As a conclusion, your organization gets a way to be recognized for its practices, which may or may not be instrumental in dealing with the stakeholders of your site. In my experience of management systems, customers/quality, workers/health and safety at work, as well as neighborhood/environment are stakeholders/management objects that generate consensus.

What You Get as a Person

Not only does your organization benefit from addressing operational risks, but you also benefit.

What's in it for Your Own Mental Health?

If you address operational risks, a number of stress factors inherent to being a site manager should disappear.

Threats of litigation involving your personal legal liability should decrease if you have a view of the entire set of obligations and are addressing, even in a basic way, each and every one of the obligations.

The set of obligations will provide you with evaluation criteria for decisions you make. The moral discomfort of not knowing if you are doing the right things should disappear.

If you lack a clear understanding of obligations and of concrete actions taken to comply with these obligations, you may have a hard time delegating some of the actions. Conversely once clarity on each obligation and on actions taken to comply with obligations exists, you will be in a position to involve the best individual to make sure that actions taken are effective.

Now you will be a more informed seeker of technical assistance and should be better able to assess the results of hired technical assistance. Furthermore, your addressing operational risks will make you seek technical assistance where it is needed and eventually discard irrelevant technical assistance.Issues found to be intractable because of their moving nature will be nailed down, once you have addressed the underlying cause residing in operational risks.

If you choose to implement continuous improvement, the healing effect of addressing operational risks will not just be a one-time benefit but one that lasts over time. Implementation of continuous improvement needs a word of caution. Continuous improvement does not strive for optimization. You will occasionally have a vantage point on the management system of your site that enables you to see an optimum. You

will not be in a position to "go for it" and will need to go through the discipline of continuous improvement.

Addressing operational risks does not only bring advantages to you as an individual, but also advantages to you as responsible for the bottom line of your site.

What's in it for Your Bottom Line?

Benefits to your bottom line are cost avoidance, additional margin from incremental business, better investment and better make/buy decisions.

Addressing operational risks will help you avoid the following costs:

- Insurers seeing your prevention efforts will classify your site as small moral hazard and lower their prices accordingly
- In some countries employer's social contributions will be lowered
- Costs associated to work slowdown and stop will be lowered
- Financing of provisions for avoidable risks
- Reputation rebuilding after worker and environmental accident perceived as negligence

The certification of your management system can and should be used as a commercial argument that generates further business from existing customers and possibly opens new accounts. Margin brought by this additional business will to some extent benefit from addressing operational risks.

The set of criteria you use to assess investments should be enriched by your new understanding of operational risks. Alternatives that might have been seen earlier as no-brainers may be seen differently once the impact on operational risk is taken into consideration.

Addressing operational risks and especially the effort put in at describing your work environment will reward you handsomely when you contract for technical assistance because you will not have to pay each provider of technical assistance to describe your work context. Furthermore, as you will be a savvy buyer knowing specifically what you need, you should benefit from positive selection of the best provider within money available.

What's in it for Your Management Repertoire?

Your management repertoire has brought you to site management. Assuming management is a performing art, you have so far convincingly played roles expected from a site management position.

Operational risk management offers you a number of opportunities to sharpen your abilities and maybe even develop new ones. These are presented here in no particular order.

You could mobilize the energy of individuals towards site goals. If there are others in your organization professing an "us in the trenches vs. they in the offices" discourse, you should make them champions of continuous improvement. These individuals are likely to be recognized as professionally competent and would otherwise be silenced by peer pressure.

Your skills at fending off bureaucracy will be further sharpened by triangulating information from operations. Triangulation[14] gives a different vantage point on a phenomenon and favors a better apprehension of reality. It could be that stubborn facts originating from operations could become visible to you, even though they are carefully omitted in regular communication because they are perceived as contradicting your viewpoints.

You possibly have formulated in your management activities statements on people, the environment, change, performance, etc. This "talking the talk" is a necessary contribution to management. Addressing operational risks and implementing continuous improvement can be used to "walk the walk" on talks you have made.

Knowing hazards on your site (what, where, when, who, how, why) will both make you an economic decision maker aware of more relevant costs and a person relating to other persons not just in a superficial way (polite, friendly, etc.) but also eventually in a way that shows an understanding of hazards the person might encounter (empathy).

Addressing the operational risks of your site will force you to steer the long-term future of your site. Taking into account all obligations will diminish the odds of having to restructure your site and have to shut down activities and lay off people.

Operational risk mastery will help you detect early weak signals in forthcoming regulation that could make your site nonviable. You will then be in a a position to embrace early voluntary measures to deter regulation or begin in a timely manner the structural changes of your site so that it does not meet inclusion criteria in regulatory texts.

14 See "In the age of the smart machine", 1988, Shoshana Zuboff published by Basic Books