



Guidelines

for the Assurance of

Safety, Security, Health and Environmental Protection in the Roche Group

2019 edition – supersedes the 2014 edition.

Obligation to Society

Excerpts from the Roche Corporate Principles:

Mission

Our aim as a leading healthcare company is to create, produce and market innovative solutions of high quality for unmet medical needs. Our products and services help to prevent, diagnose and treat diseases, thus enhancing people's health and quality of life. We do this in a responsible and ethical manner and with a commitment to sustainable development respecting the needs of the individual, the society and the environment.

Respect for the individual, Commitment to society

We want everyone in the organization to work under optimal conditions of health and safety. We want to maintain high ethical and social standards in our efforts to protect the environment.

Commitment to the Environment

As part of our commitment towards sustainable development we proactively seek to employ new, more sustainable technologies and processes and to minimize our impact on the environment.

Therefore our mission for safety, security, health and environmental protection is:

We ensure business continuity by managing Safety, Security, Health and Environmental matters with the same sense of responsibility, and just as methodically, as issues concerning quality, productivity and cost-efficiency.

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Abbreviations

- SHE = Safety, Security, Health and Environmental Protection. This is the abbreviation for the corresponding topics. See also chapter 1.2.
- Group SHE = This is the abbreviation for the SHE organizational unit on the Roche Group level.
- SEO = Safety, Health and Environmental Protection Officer = SHE Officer.
- SSO = Site Security Officer.

1. Introduction

Safety and health protection at all workplaces, together with protection of the surroundings and the environment are principal concerns of the Roche Group's management. They are main elements of a sustainable development, as pursued by Roche.

Safety, security, health and environmental matters are handled with the same sense of responsibility, and just as methodically, as issues concerning quality, productivity and cost-efficiency.

Safety, security, health and environmental protection concerns are an inseparable part of every activity. Department supervisors are responsible for ensuring that these issues are well managed. They are accountable for knowing what can be expected of employees in terms of know-how and skills and the technical and organizational measures that are required.

Every supervisor and specialist must be familiar with the laws and regulations applicable to his or her area of responsibility, as well as with internal guidelines and directives, and with recognized technological codes and implement them accordingly.

All employees have a personal responsibility, in accordance with their level of knowledge and ability, to ensure that safety, security, health and environmental protection regulations are observed.

1.1 Purpose of the Guidelines

Based on the *Roche Corporate Principles* the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group* was adopted by the Corporate Executive Committee. This policy document was revised and published in 2012; it builds on earlier editions (1980, 1991, 1996 and 2005).

In addition to the principles stipulated in the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group*, Roche also adheres to the guidelines of various international bodies. For instance, Roche has signed the Charter for Sustainable Development of the International Chamber of Commerce (ICC principles on environmental management). Roche is committed to comply with all legal requirements and the pertinent international conventions in every country where we operate.

The present *Guidelines for the Assurance of Safety, Security, Health and Environmental Protection in the Roche Group* are oriented to the ISO 14000 ff standards.

SHE is an integral part of the Roche Sustainability efforts (see <http://we.intra-net.roche.com/sites/roche/content/about-roche/sustainability/pages/default.aspx>).

The main purpose of these Guidelines is to define clearly the corporate provisions and requirements which are both necessary and suitable for practice-oriented implementation of the principles of the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group* and the above-mentioned international programs.

As a supplement to these guidelines, Group SHE or local SHE organizations may issue special documents (e.g. guidance notes, directives, annexes) on specific topics. In carrying out their work, supervisors and specialists must therefore, in addition to meeting all legal requirements, observe not only the *Guidelines for the assurance of Safety, Security, Health and Environmental Protection in the Roche Group* and the local SHE handbook, but also such additional documents on specific issues.

1.2 Scope

This publication has Group-wide validity. It is binding for all Roche Group Companies and Sites and must be followed by all managers and employees. Proposals for deviations from the provisions in this document can be discussed with Group SHE who can approve the deviations if the expected outcome is comparable to the provisions herein.

SHE matters regarding third parties are covered by the *Roche Guidelines on Dealing with Suppliers and Service Providers* (part of the *Roche Code of Conduct*) and the Corporate SHE directives K13 (*Dealing with Contractors*) and K15 (*Assuring SHE performance at suppliers and service providers*).

In order to account for the variety of businesses within the Group, the SHE provisions in this Guidelines document are formulated in a generalized manner. Companies and Sites must therefore regulate specific aspects in a local SHE handbook in line with their local organizational form and particular circumstances.

SHE stands for *Safety, Security, Health and Environmental Protection*, which comprises all issues and activities in these areas. It does not address safety issues in the intended use of our marketed products.

Relevant topical areas are exemplified below, though the list is not exhaustive:

- **Safety**
 - Operational safety
 - Employee safety
 - Accident prevention
 - Building and plant safety
 - Process safety
 - Car safety
 - Risk management
 - Emergency management
 - Safety of chemicals and biological materials
 - Handling
 - Storage
 - Transport
 - Safety data, documentation

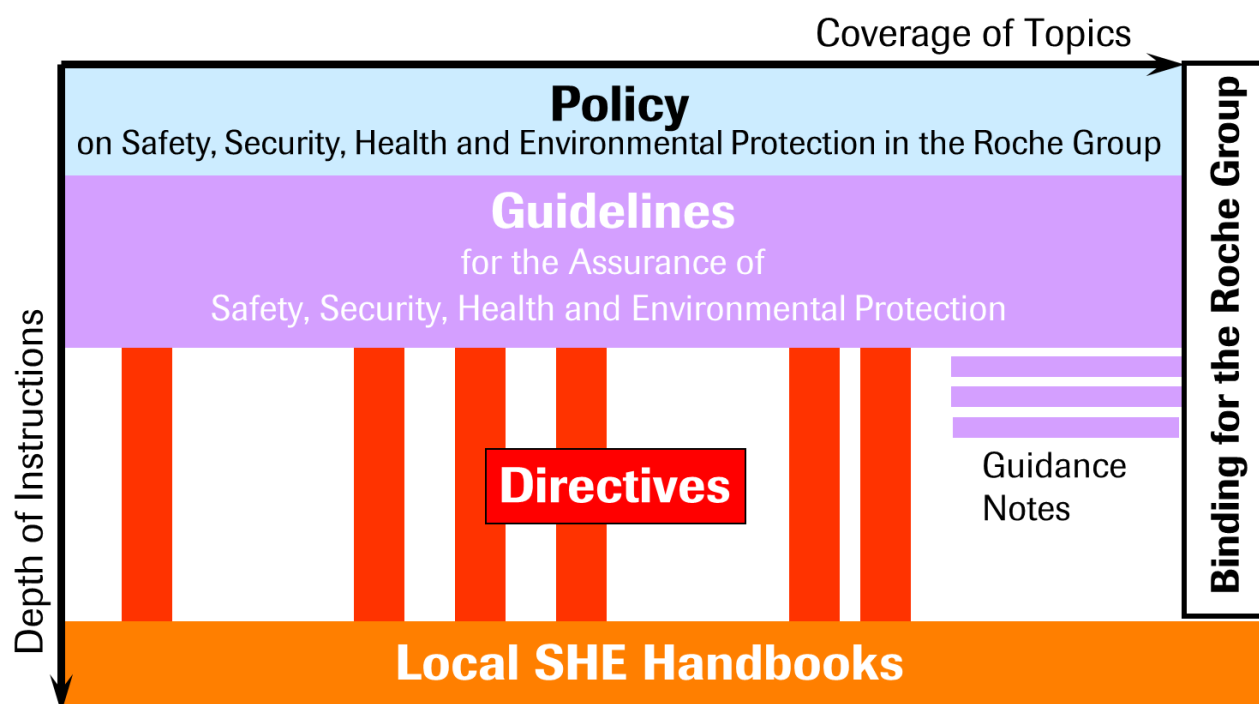
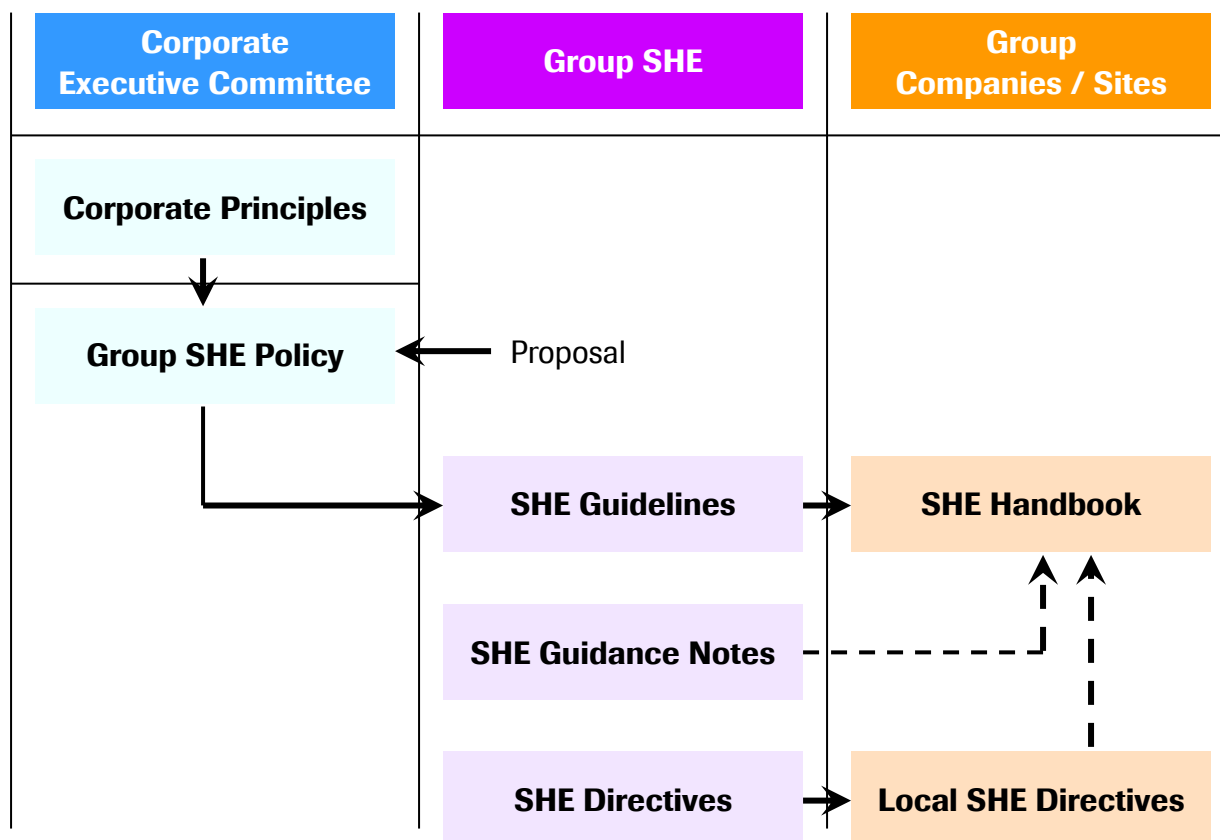
- **Security**
 - Personnel
 - Physical assets
 - Products
 - Knowledge
 - Information (not covering core IT security like data access control, firewalls, virus protection etc.)
- **Health**
 - Health protection at the workplace
 - Industrial hygiene
 - Occupational toxicology
 - Occupational medicine
 - Accident prevention
 - Ergonomics
 - Stress, mental health
 - Biosafety
 - Radiation protection
 - Noise
 - Health promotion
- **Environmental Protection**
 - Emissions
 - Into the air
 - Into the water
 - Into the soil
 - Waste
 - Avoidance
 - Re-use, recycling
 - Disposal
 - Resources, including energy
 - Efficient use
 - Change to best alternatives
 - Eco-balance
 - Noise
 - Remediation of existing contamination

1.3 Management Cycle

The management of SHE issues should be structured and clearly communicated. For this reason we encourage the use of a framework that includes each of the basic steps in a management cycle (e.g. according to ISO 14000).



1.4 Hierarchy of and Responsibility for SHE Documents



Guidance notes provide specific instructions valid only for certain parts of the organization (e.g. specific guidance for research).

Directives are explicit instructions on selected topics (e.g. on energy management). They are binding for all Roche and must be followed in detail (except if provisions are prohibited by local laws). Directives do not cover all SHE topics.

In accordance with the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group*, all Group Companies and Sites are required to prepare and maintain **local SHE handbooks**, which form the basis for the SHE management at the Site (note: SHE handbooks are typically made available electronically). These handbooks must describe in detail the implementation of the *Guidelines for the Assurance of Safety, Security, Health and Environmental Protection in the Roche Group* at the local level. In particular, the handbooks should indicate where additions or modifications must be included based on local conditions (see following list).

The following elements should be included in the local SHE handbook (existing documents can be referenced). These elements constitute the minimum necessary corporate requirements. Additional formal requirements are necessary if you strive for certification (e.g. ISO 14001, EMAS, OHSAS 18001), and they also may be necessary for local legal reasons. Additional documentation requirements are described in the SHE directives.

Introduction	- Glossary: definitions, abbreviations, terms
Site description	- Description of activities - Site organization - Site plans
SHE Organization	- Name of manager responsible for the Site - Determination of Site-specific responsibilities for SHE (job descriptions, duties) - SHE organization charts - Organization of emergency response service
Legal aspects	- Catalogue of legal SHE regulations (laws, ordinances, provisions, training), including reference to specific regulatory applicability to Site operations, as well as local compliance assurance documentation - Catalogue of SHE related building and operating licenses - Catalogue of SHE related agreements with authorities (exemptions, extension of deadlines, etc.)
Communication	- Determination of rules for internal and external SHE communication
Measurements, data	- Catalogue of compulsory and voluntary data registration (e.g. emission and immission monitoring) - Processes for key data collection and reporting

Documentation	<ul style="list-style-type: none"> - Rules on documentation of SHE related data - Regulations on distribution, updating and filing of SHE related documentation (document control and retention) - Catalogue of valid SHE documents - Cross references to other SHE related documents
Processes	<ul style="list-style-type: none"> - Description of all relevant SHE processes of the Site (sequence of activities, controls, responsibilities, documentation, etc.)

2. Strategic SHE Objectives and Operational Goals

The *Policy on Safety, Security, Health and Environmental Protection in the Roche Group* establishes the following strategic SHE objectives.

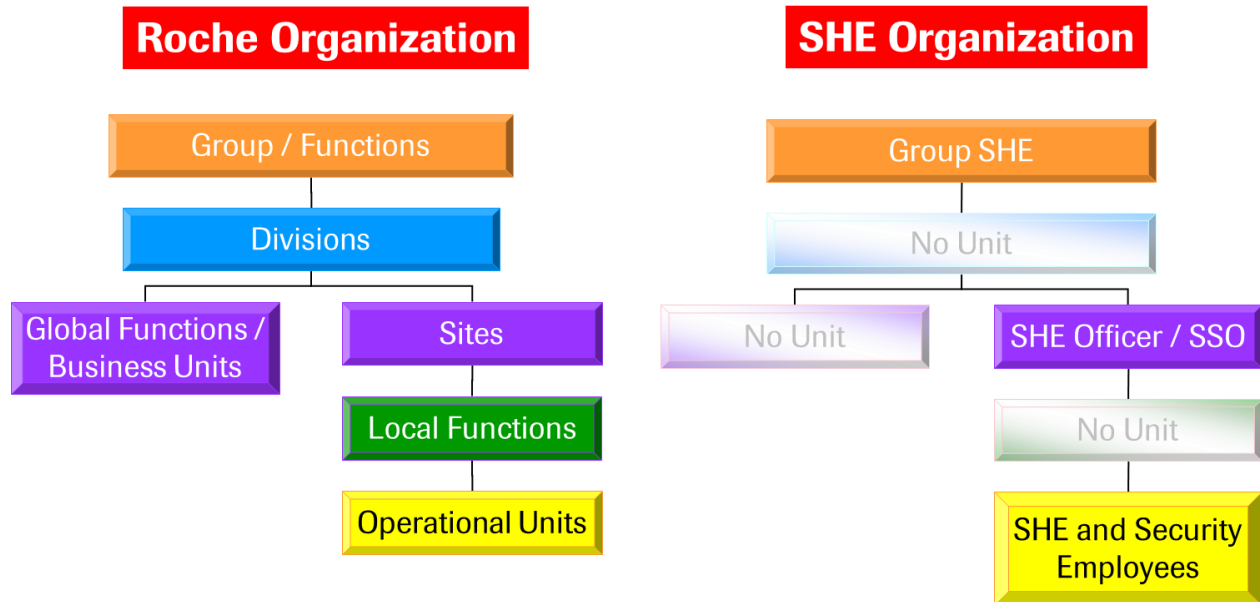
Roche strives to:

- establish itself as one of the leading companies in the healthcare industry
- continuously improve upon our high standards for safety, security, health and environmental protection
- promote SHE awareness among all employees and create the conditions for SHE to become a matter of course in their daily work
- support active SHE communication including training
- maintain good relations on SHE issues with neighbors, authorities, customers, suppliers, shareholders and the public
- continually reduce the ongoing and episodic environmental impact from our operations
- actively manage the entire SHE risk portfolio
- identify and resolve unacceptable risks at an early stage
- continue efforts to further prevent occupational injuries and illnesses
- optimize the use of all materials and energies to improve the eco-efficiency and continually reduce environmental pollution and conserve resources
- provide security for our employees, workplaces, knowledge and products

Roche has established operational SHE goals on the Group level (see <http://we.intra-net.roche.com/sites/grouplegal/content/group-she/ls-organisation/she%20goals%20for%20the%20roche%20group/pages/default.aspx>). The goals and the performance against these goals are published yearly on the Roche Internet (https://www.roche.com/sustainability/environment/our_she_goals_and_performance.htm). All Sites must make sufficient efforts to contribute to these goals according to their abilities.

3. Organization and Responsibilities

3.1 General Organization of SHE



3.2 Corporate Executive Committee

The Corporate Executive Committee (CEC) determines the SHE policy on the basis of the *Roche Corporate Principles* and the *Roche Sustainability Charter*. The CEC defines the main organizational structures and designates the functional responsibilities necessary for implementing the SHE policy. In addition it supervises compliance of the entire organization with this policy.

Safety, security, health and environmental protection are principal parts of a sustainable development and therefore main topics handled in the Corporate Sustainability Committee (see <http://www.roche.com/home/sustainability.htm>).

3.3 Committee of the Board of Directors supervising SHE

The assigned sub-committee of the Board of Directors is regularly informed about the status of SHE in the Roche Group, the SHE goals, the trends of the corresponding key performance indicators, the main SHE issues (past and foreseen), the SHE risk situation and the exposure of the Roche Group to new SHE issues and trends. This Committee provides general guidance regarding SHE and actively engages itself if the SHE status, trends or risks are deemed unsatisfactory.

3.4 Heads of Divisions, Business Units and Global Functions

The heads of divisions, business units and global functions must consider economic, environmental and social (including worker) impacts when taking business decisions. They support their organizations in their SHE tasks and duties, in particular by

- delegating the necessary powers and authority to them
- approving the necessary budgets
- ensuring that SHE due diligence is conducted on all property transactions including acquisitions, joint ventures, leases and sales of property
- involving and cooperating with the SHE organizations

3.5 General Managers, Site Managers

The General Managers (GM) of Roche's Group Companies and the Site Managers (SM) (managers responsible for a Site) are responsible for all aspects of safety, security, health and environmental protection in the areas under their control. Where certain SHE issues cannot be assigned to a single Site, but span multiple Sites, the managers responsible for the corresponding activities take this responsibility. In these cases the delineation of SHE responsibilities must be carefully coordinated.

On the basis of the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group*, these Guidelines and the Group SHE Directives, the GM/SM adopts the local SHE and security handbooks, establishes the local SHE organization and assigns responsibilities. The name of the manager responsible for a particular Site and of the persons in charge of SHE must be provided in the local SHE and security handbooks and reported to the headquarters to be documented in the Roche Corporate Addresses database.

The SHE tasks and duties of the managers responsible for a Site are listed below. The General Manager or Site Manager, while remaining responsible for SHE, may delegate certain tasks to the line managers and certain tasks to the local SHE officer and SSO.

- implementing the corporate SHE Policy and Guidelines
- defining the local SHE organization and assigning relevant tasks and responsibilities
- establishing accountability for SHE performance and goal attainment with direct reports
- promoting SHE awareness among employees at all levels, especially regarding the relevant legal regulations and in-house SHE provisions
- ensuring compliance with local legal regulations and with Roche SHE provisions
- allocating sufficient resources to support effective SHE training
- defining local SHE objectives and goals, based on the Group SHE objectives and goals
- defining and implementing action plans to address SHE objectives and goals
- ensuring that a risk analysis process is established and that identified risks for all relevant assets, workplaces and processes are adequately communicated and managed
- compiling the corresponding risk inventory (risk register)

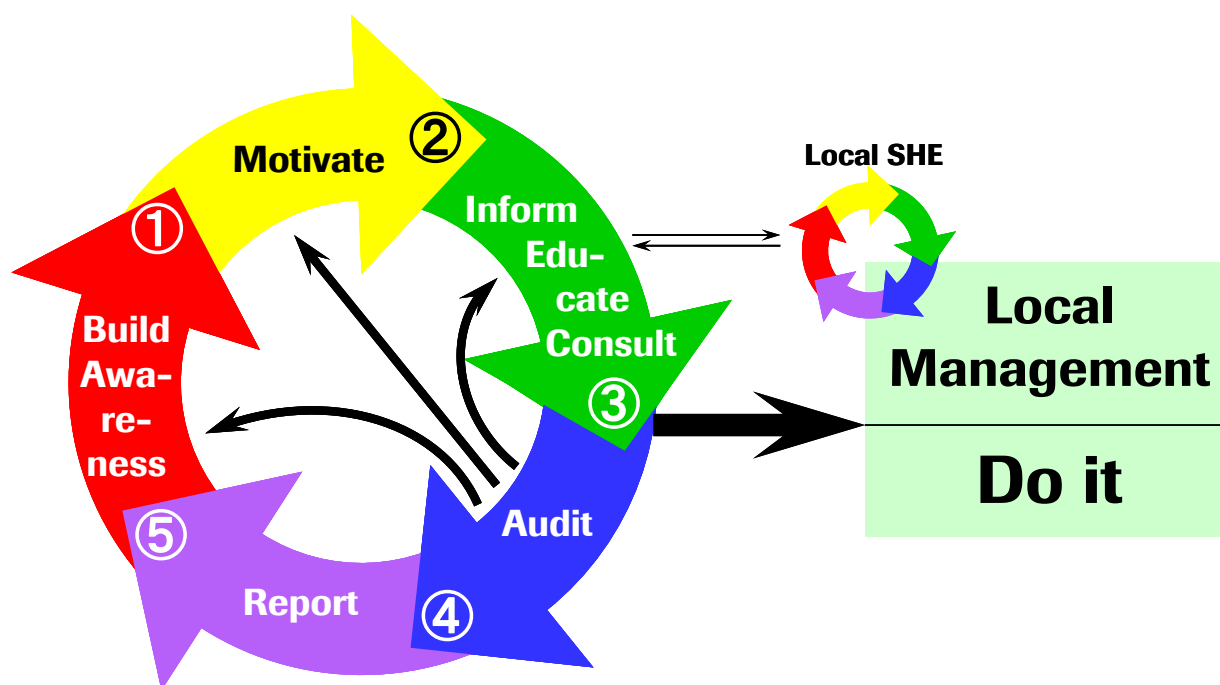
- ensuring and implementing an adequate and consistent security strategy for the Company or Site
- setting up and training of an appropriate emergency management organization in line with local risks, clearly defining responsibilities, powers and procedures
- establishing an external communication process to ensure good relations with neighbors, stakeholders and the public regarding SHE issues
- establishing a process to ensure that SHE due diligence is conducted on all property transactions including acquisitions, joint ventures, leases and sales of property
- ensuring that SHE-relevant incidents as well as situations where assistance is needed are reported to Group SHE and – where necessary – to the authorities
- preparing and updating a local SHE handbook
- ensuring that all employees are informed about and have access to the local SHE handbook and other relevant SHE information in line with their level of competence and responsibility
- periodically reviewing the local SHE management system
- ensuring that business decisions are sustainable and include consideration of economic, environmental and social (including worker) impacts
- implementing a system for management of change and for the review of capital and maintenance projects for SHE impacts
- ensuring that the SHE Officer and SSO are notified and involved early in the design phase of new projects
- ensuring that contracted service providers and suppliers are carefully selected regarding their SHE performance
- determining Site-related SHE key figures and reporting them to Group SHE

3.6 *Group Safety, Security, Health and Environmental Protection (Group SHE)*

Group SHE is a specialized Group function which supports the Corporate Executive Committee in SHE matters. It has the following mission:

Set standards and regulate SHE matters. Support implementation by

- Building awareness
- Motivating
- Educating, Informing, Consulting and Supporting
- Auditing, Checking
- Reporting



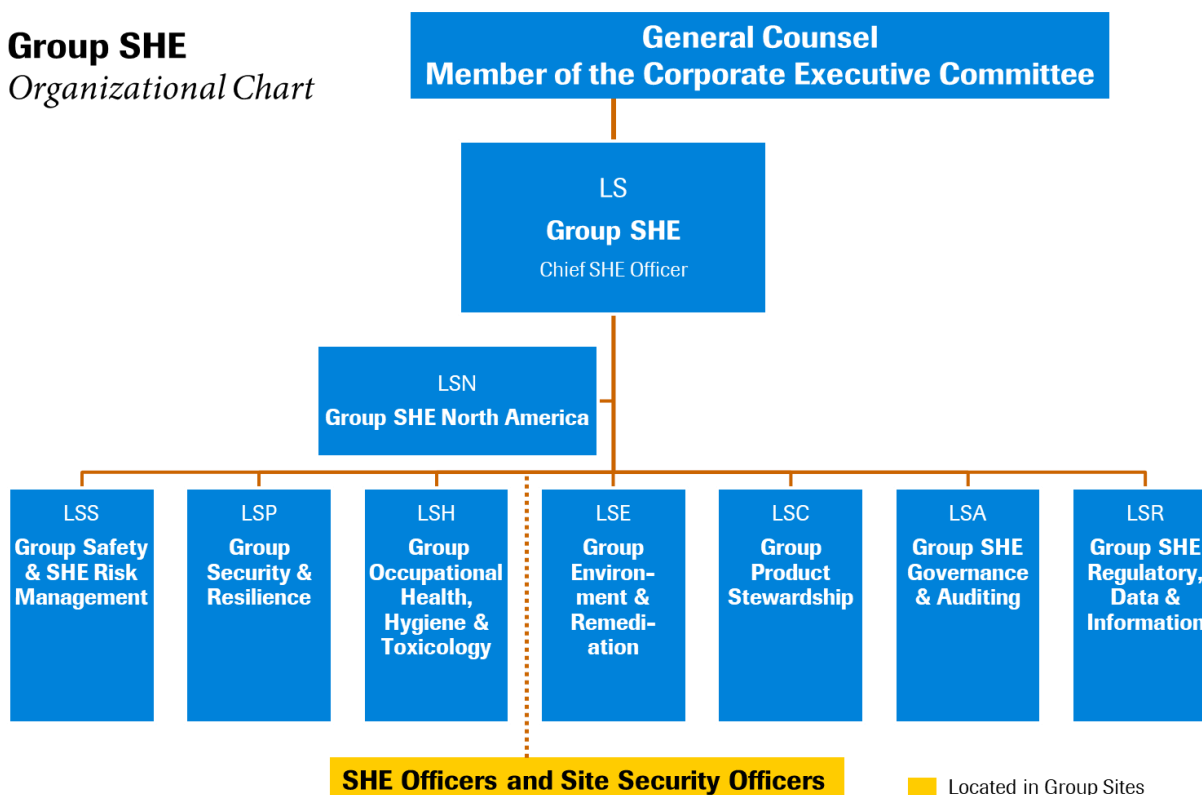
Tasks and duties include:

- formulating the corporate SHE policy on behalf of the Corporate Executive Committee
 - including periodic review and amendment as necessary
- issuing Group-wide SHE documents (guidelines, guidance notes, directives) in support of the corporate SHE policy
- identifying, monitoring and assessing the general developments in SHE worldwide and initiating necessary actions in response to emerging trends or specific SHE problems
- protecting Roche interests in governmental and non-governmental organizations, business organizations and scientific bodies while providing support in developing favorable solutions
- representing all SHE affairs in the Roche Sustainability Committee
- supporting the Group Companies and Sites in all SHE matters
 - training local SHE officers
 - discussing and assessing proposals from the Sites
 - identifying and communicating possible SHE solutions by providing the advantages and disadvantages of possible options (best practices)
 - arranging contacts with experts and colleagues
 - facilitating know-how exchange and benchmarking
- preparing relevant safety documents for chemical and pharmaceutical substances handled within the Roche Group (e.g. material safety data sheets, environmental risk assessments, classifications, registrations, etc.)

- conducting SHE audits at Group Companies and Sites to review the status of SHE and local SHE management systems and ensuring follow-up
 - assessing the corresponding corrective action plans
 - monitoring implementation of the corrective actions
- performing due diligence to identify SHE risks and liabilities associated with property transactions (e.g. acquisitions, joint ventures, leases, sale of parts of our business etc.) in support of, and upon request from General and / or Site Management
- preparing a Group SHE risk inventory based on the local risk inventories and overall global risks
- collecting SHE key figures and other relevant information from the Group Companies and Sites
 - conducting plausibility checks
 - consolidating of the numbers on different levels
- coordinating corporate security programs and addressing security issues that cannot be resolved at a local level
- informing the Corporate Executive Committee and the Committee of the Board of Directors supervising SHE of the SHE status and the relevant SHE risks in the Group
- preparing the SHE section of the annual Roche Business Report
- maintaining Corporate SHE Internet and Intranet pages
- issuing Corporate position papers on important SHE topics, and SHE bulletins on critical issues

Group SHE consists of colleagues located at Roche Group headquarters in Basel (LS = Group Legal, SHE) and in the USA (CESA = Corporate Environmental and Safety Affairs). The head of Group SHE has the global responsibility for the described SHE tasks.

Group SHE Organizational Chart



3.7 Local SHE Organization, SHE Officers, Site Security Officers

Every Roche Site must designate a SHE Officer (SEO) and a Site Security Officer (SSO) who are located at the Site. Group SHE must be involved in the selection process (information on and interview with final candidate); they have a right of refusal, but the General Manager / Site Manager is finally deciding on who will be the SHE Officer / SSO.

The tasks and competences must be given to them by the General Manager / Site Manager in writing (e.g. in a job description). In small Sites the two roles may be taken by the same person. The SEO and the SSO may be supported by a specialist SHE organization. Since the Site SEO and SSO need to

- be as independent as possible,
- have direct, unfiltered access to the top management of the Site,
- have real oversight over the Site, and
- have influence on the whole organization,

they typically report directly to the head of the Site (exceptions to be discussed with and approved by Group SHE).

In respect of technical matters, the SEO reports to the head of Group SHE and the SSO reports to the Chief Security Officer at Group SHE. Depending on a Company's size and the complexity of its operations, the local SHE organization may be expanded. At small Company Sites these tasks can be conducted by single employees as part of or in addition to their regular responsibilities.

The tasks and duties of the local SHE organization and the local SHE officer include:

- supporting and advising Site senior and line management in SHE matters
- promoting SHE in the Company based on the local and global Roche SHE objectives and goals
- supporting the organization for compliance with local legal regulations and with Roche SHE provisions
- supporting line management in SHE training for employees
- developing and maintaining a system for receiving, documenting and responding to SHE related reports and complaints
- ensuring that a risk analysis process is implemented and documented
- timely and actively representing and defending SHE requirements in projects and ensuring their implementation
- conducting periodic SHE inspections
- reporting critical SHE situations
- monitoring and documenting
 - the implementation of SHE programs and action plans, especially SHE measures planned in order to close identified gaps
 - accidents and incidents,
 - occupational injuries and illnesses,
 - emissions due to the activities of the Company, especially related to soil, water and air pollution
 - the use of energy and raw materials and specifically regulated items
 - the status and progress of actions related to SHE goals and targets
- compiling and documenting the SHE KPIs
 - used for monitoring the trend towards the SHE goals
 - used by the management as a basis for their SHE plans
 - for SHE reporting
- reviewing and supporting the communication of SHE related information and documentation
- advising local (Roche external) emergency response teams in the event of incidents, including transport accidents involving Roche products
- establishing and maintaining the local (Roche internal) emergency management (LEM) system
- managing financial provisions for legacy health and environmental liabilities, together with the finance department
- establishing and maintaining contacts with the local SHE authorities, professional organizations, scientific bodies and the public

The tasks and duties of the local security organization and the Site Security Officer include assessing and assuring that adequate security programs are in effect to address

- the security of Roche employees (on Site and outside the Roche premises), including, among others, travel security, evacuation planning and kidnap plans, etc.
- the physical protection of the buildings, plants and properties, including, among others, fences, doors, closing systems, reception desks, security guards and patrols, detection and alarm systems, etc.
- the control of contractors and visitors
- the protection of intellectual property and proprietary information
- the transportation of high value shipments

The Company and Site management respectively are accountable for the security concept and the defined protection levels. Operational elements of Site security (e.g. security patrols, guards, etc.) may be outsourced to reliable companies if there is a clear business case (not just head-count). For more details see the Group SHE Directive K19.

Safety and security programs often overlap and the two functions must work closely and effectively together. Therefore the safety, security, health and environmental protection functions should form a common department (while historical exceptions having security as a separate local function are allowed).

The specialist SHE organization, the SHE officer and the SSO may assume certain additional tasks delegated by the General Manager or the Site Manager.

Each SHE Officer and SSO must have a deputy. In case the SHE Officer or SSO function is taken over by another person, a smooth hand over of the SHE and security documentation and affairs to the new job holder must be ensured by the line management.

3.8 Line Managers, Supervisors

Roche places direct responsibility for initiating, implementing, monitoring and supervising SHE with the line managers of the various areas and departments - within the scope of their decision-making powers.

The tasks and duties of line managers / supervisors include:

- developing and maintaining knowledge of and ensuring compliance with company policies, guidelines and directives as well as local SHE regulations
- implementing SHE programs
- defining SHE goals and objectives in support of Group and Site targets
- preparing and maintaining area-specific documents for the operation and maintenance of plants, installations, equipment and buildings as well as for production and other work processes; ensuring inclusion of safety, security, health and environmental instructions into work instructions and standard operating procedures (SOP)
- assuring that SHE training processes are in place, that employees are attending training, and that training is adequate for employees to conduct their job responsibilities
- providing all necessary SHE information to the employees

- assigning work in line with employee aptitude and training, and supervising working procedures
- setting an example for employees by frequently discussing SHE and intervening in case of unsafe work practices and conditions
- arranging for workplace risk assessments, industrial hygiene monitoring and periodic medical examinations of employees where / when applicable
- escalating SHE issues they cannot solve / decide to higher management levels

3.9 Employees

Within their particular sphere of activity, all employees are expected to perform their duties to the benefit of the Company, using common sense and the best of their knowledge. They are personally responsible for SHE in line with their know-how, skill and experience. They are required to learn and follow all programs, procedures and instructions relating to SHE, to report unsafe conditions or acts and to inform their line managers / supervisors if they are uncertain or unable to deal with a particular situation.

3.10 Additional Positions with Safety, Security, Health and Environmental Protection Responsibilities

Specialists may need to be appointed for particular tasks or due to legal regulations in certain areas. They are responsible for the technical accuracy of their work. The line managers are responsible for taking due notice of the information given and for the appropriate implementation of specialists' recommendations.

- **SHE Building Officer:** For larger Sites with many buildings and a big number of employees it is recommended that for each building a person responsible for SHE matters is appointed. His or her tasks and duties should be defined in the local SHE handbook.
- **Occupational Health Services:** Each Group Company or Site must provide a medical service responsible for necessary examinations and evaluations that may be required by local regulations or by Roche provisions (including for prevention). In addition, this service should be available to treat employees who have been injured or become ill while on the job. This function may be outsourced.
- **Other Officers for Special Tasks:** Depending on local needs, regulatory requirements (including requirements defined by Roche Group Directives) and the nature of the hazards at the Site, some Group Companies and Sites may appoint
 - bio-safety officers,
 - radiation protection officers,
 - officers for toxic, addictive and / or narcotic substances,
 - transport safety advisor, etc.

These roles must be included and defined in the local SHE handbook.

- **Onsite Emergency Response:**

- A certain proportion of the staff of the Site should be trained as first aiders.
- Depending on the local need, a number of employees may be trained as volunteer fire fighters and / or as members of local emergency response teams.

3.11 Third Parties

Whenever employees of outside companies (third parties) are working on Roche premises, a Roche responsible party must be designated and suitable measures must be taken to ensure that these companies

- have been pre-qualified to perform the work being requested
- work under the same standards of SHE as Roche personnel
- are properly supervised while on Roche property
- have the necessary personal protective equipment (PPE) available as needed

Employees of these companies must

- have received instruction or orientation regarding the worksite, the SHE regulations to be observed, the emergency measures to be followed and specific permit procedures
- have the necessary knowledge about specific SHE requirements of their work (e.g. proper earthing/grounding, required air flow in a hood, proper lighting etc.)
- have a clear work order with clearly defined limits and information about related or nearby hazards
- be familiar with available safety and protective equipment (provided by the third party or by Roche) and are instructed in its use
- be familiar with and committed to observe the legal regulations and applicable Roche-specific SHE provisions

The local SHE organization is generally responsible for developing the SHE program to address outside companies and for gathering the KPIs of the outside companies (such as the Contractor Accident Rate). The Site Manager defines those responsible for the day to day supervision of the third party company on Site. Detailed provisions are stipulated in Group Directive K13 (*Dealing with Contractors*).

3.12 Further information

For more information please see our Intranet (<http://rochenet.roche.com/cse>) and internet pages (<http://www.roche.com/sustainability.htm> and subpages thereof).

4. General SHE Standards

4.1 Training

SHE training is essential in order to assure the necessary and desired SHE awareness and performance level. It provides employees with the knowledge they need to perform their work safely and effectively and must be adapted to the special circumstances and job functions involved. Line management is directly responsible for the training of their employees. Managers are required to designate the training that is required in order to perform the work and to mandate and track attendance at the training programs. The local SHE organization support them in this task as needed. All SHE training must be documented.

For SHE training of contractors see Chapter 3.11.

4.2 Communication

The Group Companies and Sites ensure internal communication in the field of SHE and the flow of information to Group SHE. They arrange for SHE information to be distributed to employees (including those working outside the premises, e.g. sales representatives) and contractors in line with their function and needs. These communication processes and regulations are to be established in the local SHE handbook.

External communication on local affairs is the responsibility of the managers of the local Group Companies and Sites. They must ensure that their statements be in line with the Corporate SHE policies and communication and be based on the general principle of open dialogue with all stakeholders. When questions arise, they contact Corporate Communications (CC) or Group SHE for advice. At Group level, Corporate Communications (CC) is in charge of external communication of SHE matters in close collaboration with Group SHE.

Group Companies or Sites can engage in SHE knowledge exchange and benchmarking with other companies or with professional associations. This is explicitly encouraged in order to maintain our high level of SHE competence, but participants must ensure that all antitrust requirements and other legal provisions are respected (refer also to the Roche Behaviour in Business regulations).

Group Companies and Sites maintain contacts with the authorities and exchange all required and otherwise useful information with them in the sense of open dialogue and cooperation, while fully complying with Behaviour in Business regulations.

Where necessary (e.g. for members of the local emergency management team) people in charge of SHE are trained in the principles of media communications.

4.3 Goal Setting, Performance Monitoring and Key Data Collection

Based on the principle of continuous improvement, SHE goals are established at the Group level. These goals shall be cascaded down the organization to support the Group goals. The goals must fulfill the criteria of SMART goals (specific, measurable, achievable, relevant, time based), and clear responsibilities must be assigned. Action plans for attaining the goals must be elaborated and implemented.

SHE goals should be documented and measured as part of the performance management system.

For the assessment of SHE performance and trends, key data must be collected according to defined rules and definitions and consolidated at various levels, including at the Group level. Legal requirements, authorities and rating agencies may also require reporting based on this data.

SHE key figure reporting (as part of the annual Roche Business Report) is an annually recurring process. The system and the numbers are regularly verified by an independent third party.

It is crucial to have processes in place which ensure a high quality of the key figures reported. The data is used locally for informing the SHE activities and on all levels for internally and publicly reporting our activities and performance. Inaccurate, incomplete or false numbers could have significant negative effects on Roche.

If definitions given by Group SHE for corporate reporting do not satisfy national or local (legal) requirements, data reporting meeting each set of definitions must be elaborated and reported accordingly. Such local definitions and the frequency and process of data gathering (including for Roche internal reporting) must be documented in the local SHE handbook.

4.4 Documentation and Document Distribution

SHE related data must be consistently recorded and reported and must be collected according to defined rules. These rules are to be listed in the local SHE handbook. Special attention must be paid to sensitive data (especially personnel data) and compliance with pertinent data protection requirements.

A process must be established to assure that documentation requiring periodic update is reviewed as necessary, and such made available as appropriate to employees, relevant authorities and government bodies. This process must include a document (paper and electronic) retention procedure that considers applicable legal requirements and the Roche records retention policy.

High value records must be maintained in a safe and secure location.

4.5 Legal Aspects

Each Group Company or Site shall prepare – as part of the local SHE handbook – a list of all SHE requirements (e.g. laws, ordinances, orders, permits, agreements and conditions) applicable to all business operations and facilities. This list must be kept up to date, made available and actively communicated internally as appropriate.

Effective programs and processes must be implemented to ensure compliance with all legal SHE requirements without exception.

4.6 SHE Management System

The system described in the Corporate SHE policy, guidelines and directives and the local SHE handbook and other SHE documents form the Roche SHE management system. This system corresponds to the relevant requirements of standard SHE systems such as ISO 14001, OHSAS 18001, SA 8000, EMAS, Responsible Care® and others. Roche does not require Sites to get certification regarding such management systems when they are not required by law, but Sites may wish to obtain such certificates based on local considerations. Adoption of these external management systems must be carefully considered as they can impose significant burdens on a Site's resources. A SHE management system should

- be simple
- reflect, guide and organize the SHE programs that are in place
- identify and resolve key gaps
- maintain compliance
- create value by keeping the focus on the SHE programs at the Site

Roche is committed to sustainable development. See the Roche Sustainability web page for details of the concept and its application at Roche (<http://www.roche.com/home/sustainability.htm>).

Roche also follows the principles of Responsible Care®, an initiative of the chemical industry aimed at encouraging voluntary improvements in the SHE field. For details see <http://www.responsiblecare.org/>. The technical operations Sites are free to sign the corresponding charter in their country via the country's chemical industry association and thus also following all formal requirements of that charter.

4.7 Prevention

According to the *Policy on Safety, Security, Health and Environmental Protection in the Roche Group* prevention must be the primary focus of all SHE measures and activities. Therefore, all reasonably feasible technical, organizational and personnel measures should be implemented to manage risks for personnel and business operations and minimize potential consequences from

- occupational injuries
- vehicle accidents
- exposure to hazardous substances or physical strain
- explosions, fires
- substance releases / emissions
- damage to physical assets, and
- loss of critical business knowledge and information

Risks should be eliminated or reduced, as far as reasonably possible by substituting with less hazardous substances or by modifying processes, working procedures and installations (integrating SHE into processes). Prevention includes consideration of the SHE capability of suppliers, service providers and distribution partners.

4.8 Risk Management

Roche has developed and implemented a systematic process to assess SHE risks for all its operations and activities. This process has been detailed in Group Directive K9 (*Risk Management*). The basic steps in this methodology are:

- **Context and basic data:** Identify the details of the assessed system, establish all necessary underlying data and establish SHE risk levels against which the significance of risks is to be evaluated.
- **Safe process conditions:** Define the acceptable risk ranges in terms of people, environment and business (to be determined by the management) and identify the process parameters for how the system should work safely.
- **Hazard identification:** Systematically search for and identify hazards and identify what can happen, where and when.
- **Scenario development:** The scenario forms the link between hazards and risks. Develop and describe scenarios for each hazard identified. Analyze exposure to these hazards and / or the probability that the hazards materialize, and their resulting consequences and define why and how it can happen.
- **Risk rating and evaluation:** Characterize the resulting risks in terms of likelihood of occurrence, severity or consequence of the outcome and decide on acceptability.

- **Risk reduction:** For all unacceptable risks, develop appropriate and cost-effective measures to eliminate, prevent or reduce the consequences and/or its likelihood. Determine whether and to what extent the risks must be reduced, based on the defined acceptable risk ranges.
- **Residual risk:** Re-evaluate the risks by considering the impact of implementing the risk eliminating or reduction measures. If necessary, define what remaining risks are to be retained.

All steps must be performed by knowledgeable and trained people.

All relevant risks of a Site must be documented in a Site risk inventory. The overall exposure of the Site and activities planned to reduce the risk must be regularly presented to local and divisional management and available for Group SHE review. Group SHE will consolidate this information and report to Group management.

Relevant risks of the Site should be communicated in an appropriate way to all affected employees, community partners and the public with particular concerns. Such communication has to be done in a way that the risks are not aggravated by it.

4.9 *Emergency Management*

Various organizational, personnel and technical measures may be necessary to manage emergency situations, incidents, breakdowns and accidents. All Site's active units that are deployed, depending on the type and extent of an incident, are grouped under the emergency response service, whose staffing, response capabilities and equipment varies according to the Site's operational risks and credible emergency scenarios.

In the field of emergency management the following principles and procedures in particular should be observed:

- Provide and organize an emergency response service consisting of an internal emergency management staff and the appropriate internal and/or external operational elements for optimum response, according to local requirements.
 - Ensure availability (internal or external) of the necessary fire brigade and emergency medical service capacities.
 - Clearly define responsibilities and powers of the involved functions.
- Ensure an appropriate alarm organization in line with local needs and an appropriate around-the-clock emergency response.
 - Make sure that the communication tools are working also in case of a disaster (power outage, fire, earthquake, break-down of computer systems (Voice-over-IP telephony!), etc.).
- Guarantee that the emergency response service is well prepared through regular training and drills and through acquisition and maintenance of the necessary technical equipment.

- Prepare and update necessary documentation including organization charts, contact details of relevant persons, Site maps, intervention plans, documents on special hazard potentials, etc.
 - In particular prepare and plan for a quick, efficient and orderly disaster recovery for business critical activities through proper business continuity management (BCM). For BCM follow the process as given by the Group BCM department (roll-out started in 2014). The SHE Officer has an important role to play in BCM (risk analysis, local emergency management).
- Safeguard the flow of information to internal and external units – in particular between the Local Emergency Management (LEM) and the Group Issue Taskforce (REMOS = Roche Emergency Management Organization and Support) in case of a major incident – as well as the communication with authorities and the public.
 - Pre-establish all potentially necessary contacts to supporting organizations, the police and the authorities.
- Train all employees about potentially hazardous incidents that may occur in their work areas, along with the expected response actions they may need to take. Building evacuations in particular should be planned and practiced periodically.

4.10 Auditing and Inspection

4.10.1 Group SHE Auditing

Group SHE conducts SHE audits at the Roche Sites as follows:

- Define the audit methodology and SHE elements to be covered.
- Determine the audit frequency for the different types of Sites and for the individual Sites, based on risk potential, strategic importance, past and actual SHE performance, and other unique circumstances.
- Conduct the audits.
- Document all findings and recommendations in a formal report. Make this report known to the management.
- Require that the Site develop a corrective action plan.
- Verify and enforce implementation of the corrective measures.

4.10.2 Site SHE Self-Audits

The local SHE/security organization must conduct regular SHE self-audits to identify SHE program gaps and opportunities for continuous improvement.

External specialists should be considered on occasion to support these self-audits.

Results of these self-audits must be communicated to Site Management.

4.10.3 Local Walk around Inspections

Management should organize their own regular local rounds of SHE inspections throughout all their areas of responsibility.

4.11 Product Stewardship

Product Stewardship is the collection of actions taken to ensure that our medicines and diagnostic products are developed, produced, used and managed at end of life in a responsible manner. This requires that our SHE principles be integrated into all aspects of a product's life cycle. These principles are addressed in a variety of ways within the Group SHE Guidelines, Directives, and Position Papers.

Meeting the following overarching expectations is essential:

- Integrate SHE in Product Design: Sustainability and the conservation of resources should be considered in design specifications of products and packaging. This can be accomplished by
 - encouraging recycling, remanufacturing, and reuse in product and packaging material selection,
 - enabling disassembly and product component separation for our diagnostic equipment and pharmaceutical delivery devices, and
 - designing for lowest material and energy consumption when using our products.
- Reduce Toxicity: Materials of lower toxicity should be used in products and packaging to minimize human health and environmental risks.
- Minimize energy and resource consumption: Energy and resource consumption should be reduced in the production, distribution and use of our products to also reduce waste and emissions to the environment. Group Directive K18 provides guidance on energy conservation expectations within Roche.
- Manage and communicate SHE risks: Risk analyses (Group Directive K9) should be extended beyond manufacturing to include the management and communication of SHE risks, covering distribution, product security (counterfeiting), and the responsible use of our products once in the marketplace. All hazard information (e.g. safety data sheets, safety instructions) must be provided to stakeholders to enable effective risk management.
- Provide guidance on end-of-life issues: Guidance on end of life solutions (e.g. re-use, recycling, appropriate disposal practices, use of take-back programs) must be communicated to customers/end users through labeling and other customer instructions. Incineration is required for unused pharmaceutical product disposal, as landfilling of chemical wastes is prohibited by Roche policy. Disposal of diagnostic analyzers must be organized in a manner that does not endanger waste handlers. For more details see Group Directive K17.

Due to the far reaching and diverse nature of Product Stewardship, a variety of functional areas must play an integral role in addressing these expectations. These functional areas include, but are not limited to: Product Development, Process Development, Packaging Development, Device Development, Manufacturing, Logistics, and Security.

4.12 Due Diligence

Ensuring that potential SHE risks and liabilities are identified and considered as part of the decision-making process regarding acquisitions and similar transactions is an essential aspect of an effective SHE management system. In addition to serving to minimize liabilities associated with contaminated properties and reduce the potential for compliance problems associated with the operations of newly acquired businesses, an effective process in this area provides value to the negotiation process by identifying potential remediation and compliance issues which can then be incorporated into the negotiation. It is important that due diligence is performed for all property transactions, including acquisitions, joint ventures and leases, at the earliest possible stages of the transaction.

Supporting the due diligence process of third parties who plan to acquire parts of our business or properties is likewise important, ensuring a well-defined base line for further negotiation.

Annex: SHE Principles and Procedures

The following list gives concrete provisions for the practical implementation of the Guidelines. More details are given in the Guidance Notes and the SHE directives.

A.1 People

The following principles and procedures should be observed:

A.1.1 Health Hazards and Occupational Risk Management

- Conduct workplace health risk assessments.
 - Find and document workplace health hazards, exposures, and occupational risks.
 - Assess these risks (including those for passers-by).
 - Define and implement any necessary corrective and risk mitigating measures.
- Conduct occupational medical evaluations and exams.
 - Determine the general health status.
 - Determine fitness for duty.
 - Ensure early detection of adverse health effects from the workplace.
 - Provide medical advice.
 - Archive the data relating to industrial hygiene and occupational medicine for a minimum of fifty years.

A.1.2 Occupational Safety and Health Protection

- The organization shall implement and maintain a process for achieving feasible risk reduction based upon the following preferred order (i.e. hierarchy) of controls:
 1. Eliminate the risk by removal of the hazard.
 2. Substitute with less hazardous materials, processes, operations or equipment.
 3. Reduce the risk by technical measures (i.e. engineering controls).
 4. Provide effective warnings.
 5. Reduce the risk by organizational measures (i.e. administrative controls).
 6. Use personal protective equipment (PPE).
- In first priority reduce the potential impact
- In second priority reduce the probability

- Protect health and integrity of people from damage by chemicals, biological materials or physical effects (occupational safety).
 - Carefully assess material properties. Document the findings in safety data sheets and in operational procedures and take them into account in risk analyses.
 - Define permissible exposure levels according to recognized exposure standards set by relevant authorities and internal Roche standards and categorizations, in particular for
 - chemicals, biological materials
 - radioactivity, ionizing radiation
 - electromagnetic radiation and fields
 - noise
 - heat, cold
 - vibration
 - exposure to forces (lifting restrictions)
 - light, infrared and ultraviolet light, lasers
 - Monitor the exposure levels.
 - Work with biological materials in compliance with Group Directive 17.
 - Specifically consider the heightened susceptibility of pregnant women or women in childbearing years.
- Inform and instruct employees (including the supervisors and employees of outside companies working on Roche premises or under Roche supervision) on health risks and protective measures.
- Perform regular workplace inspections to ensure that the protective measures are strictly followed.
- Establish special approval procedures for tasks involving risks, such as welding, electrical work, work at elevated height, work in confined spaces, etc.
 - Include contractors in these procedures.
- Ensure good housekeeping.
- Maintain a formal program for preventive maintenance for all buildings, plants, installations and utilities and in particular for all SHE items.

- Ensure ergonomically appropriate workplaces.
 - Apply principles of ergonomic design when planning new workplaces. In particular, among others,
 - ensure that office standards as recommended by subject matter experts are followed (available space per employee, natural light, noise, privacy). It is known that open space offices significantly reduce productivity and increase absenteeism.
 - Make available the necessary means, tools and utilities.
 - Install ergonomically designed furniture and computer workplaces.
 - Source vehicles that provide ergonomic benefits (e.g. fully adjustable driver's seat, trunk/boot depth and lift over height for safe loading and unloading of equipment and material).
 - Ensure proper illumination.
 - Avoid repetitive strain.

A.1.3 Mental Health

- Avoid unhealthy stress (distress). Good leadership styles (including delegation, participation, recognition, information) help to reduce stress.
- Protect against harassment and discrimination (cooperate with HR department).
- Protect against monotony.
- Provide assistance to and opportunities for aiding distressed employees.
- For more details see Annex 5 to Group Directive K1.

A.1.4 Health Promotion

- Provide health promotion education and activities for physical and mental health.
- Inform about health topics for the private lives of employees.
- Consider additional health promotion activities like employee assistance programs, maternity protection, fitness centers and sports activities as appropriate for your Site.

A.1.5 Rehabilitation and Reintegration

- Facilitate return to work after illness or accident.
 - Offer alternative duties or initial restriction of work-time to ease the transition back to work.
- Make sure you detect addicts and professionally support alcoholics and people addicted to other substances to control these habits.

A.1.6 SHE Knowledge

- Establish and define the necessary levels of SHE knowledge and competence for an individual job or task.
 - Determine the individual needs based on legal and job requirements.
 - Establish a training matrix to identify and record all SHE training requirements for a given job title or job task.
- Provide the necessary SHE education.
 - Provide basic SHE training to all Roche and contractors' employees.
 - Establish a SHE training process to assure
 - that necessary training courses are developed and offered,
 - that employees and contractors under your direct supervision are attending these required courses within established timeframes, and
 - that the training courses have the necessary effect.
 - The training process must include a system to document all training.
 - Use in-house and / or external training opportunities.
- Ensure that employees have easy access to important SHE information and literature.
- Create and sustain a culture that heightens awareness and motivation for SHE (e.g. through regular written or verbal updates, presentations, etc.).
- Provide advice in SHE questions and inform about best practices.
- Evaluate opportunities for internal and support of external SHE research (e.g. collaboration with universities, support of governmental or non-governmental organizations).

A.1.7 Personnel Security

- Protect employees from criminal acts during work (threat calls, direct attacks, kidnaps, bomb mails, intimidations), particularly in high risk countries.
- Provide conflict resolution training to customer service representatives (call center and field).
- Brief expats and employees travelling to risk countries on dos and don'ts.
- Give support to employees and their families intimidated or attacked at their private homes by political activists.

A.1.8 Safe Driving

Roche employees who may drive any vehicle for company purposes (cars, vans, lorries, trucks, coaches, buses and two-wheelers purchased or leased by Roche and /or rental or privately owned vehicles driven by employees while on company business), either routinely or occasionally, must be informed of the following safe driving information.

- All vehicle occupants must use seatbelts (driver and passengers). Drivers are responsible for ensuring that all passengers wear seatbelts.
- All Roche drivers are expected to comply with applicable road traffic rules and speed limits, to adapt the speed to the current circumstances and to maintain appropriate following distances.
- Employees must not operate a vehicle when drowsy or under the influence of drugs, alcohol or medication that may impair their ability to make decisions and operate the vehicle safely.
- Any activity that diverts a driver's attention away from the primary task of driving must be avoided. In particular, due to the high risk of a motor vehicle crash, employees must never text, read or reply to a written communication while driving, post to social media, handle the audio equipment or the GPS system, or use a hand-held mobile device for phone calls. If you need to operate such systems then pull up to do so. We strongly advise against the use of hands-free cell phones while driving. Where allowed by local legislation, and where there is a clear local business case, drivers may use a vehicle installed, hands-free device (not wired/wireless ear piece systems) to acknowledge short incoming calls, but only when driving conditions are favorable and safe to do so.

Each Roche organization must take formal action to ensure that all employees are provided with the above information and guidance upon hire and annually thereafter.

A.2 The Environment

The following principles and procedures in particular should be observed:

A.2.1 Safety of Chemicals

- Reduce risks by replacing highly hazardous chemical substances with less dangerous substances. Consider all types of hazards (e.g. reactivity, toxicity, mobility, persistence, potential for environmental damage, public acceptance, etc.) and the reliability of the assessment when comparing the substitute chemicals with the initial solution.
- Develop processes to ensure safe and correct labeling, transport, storage, handling and disposal of all chemicals, with special emphasis on dangerous goods.
- Support / comply with local and international risk reduction programs for substances which constitute a potential threat. Evaluate all existing operations and planned future operations to be certain that both anticipated releases of all substances to all media and potential accidental releases do not pose unacceptable risks to individuals and to

the environment. Roche-specific programs for replacing such substances will be set up on a case-by-case basis.

- Monitor and properly manage chemicals, biological materials, special equipment and know-how which can be misused as starting materials or for the production of chemical or biological weapons, bio-terrorism, recreational drugs and narcotics or are subject to international supervision for other reasons, according to local legislation and the relevant in-house provisions.
- Develop processes for chemical waste minimization, including for outsourced productions.
- Evaluate processes to minimize risk in the supply chain by reducing or eliminating the unnecessary shipment of chemicals, particularly dangerous goods.
- Chemicals are heavily regulated in most jurisdictions. Make sure that a process is in place to know all applicable laws and regulation, to recognize changes, to check compliance and to implement the necessary processes and activities.

A.2.2 Control of air emissions and water and soil contamination

- Take the necessary measures according to the following priority list:
 - Prevent the generation of pollutants / contaminants.
 - Reduce quantities of pollutants / contaminants generated.
 - Control the remaining emissions / contaminations in order to meet all legal and internal and risk based standards.
- Maintain a complete air emission / water and soil contamination inventory for your Site and all source operations.
- Obtain all required operational and construction permits for air emission and water and soil contamination sources.
- Maintain a continuous improvement program for production processes (air emissions and water and soil contamination considerations must start at the process development level).
- Control the generation of air pollutants / water and soil contaminants at the source whenever possible.
- Where applicable pre-treat the waste streams to avoid impairment of the functioning of end-of-pipe equipment and processes.
- Ensure all air pollution, source emission and water and soil contamination controls and processes impacting air emissions and water and soil contaminations are properly operated, maintained and supervised.

A.2.3 Clean Soil

- Maintain adequate systems, installations and procedures to avoid accidental or insidious contamination of the soil.
- Avoid landfilling of wastes that can be destroyed (i.e. rendering non-hazardous) or beneficially recycled.
- Identify soil and groundwater contamination caused by our prior operations or by former property owners who operated on Sites now owned by Roche. Identify landfills where Roche or acquired companies have deposited hazardous materials that may present unacceptable risks.
 - Assess the extent of contamination, risk and liability caused by this contamination or in these landfills.
 - Where necessary, work with authorities and other responsible parties to remediate or secure the Site according to local regulations and Roche provisions.
 - Establish the permissible residual contamination.
 - Determine data on the physico-chemical and toxicological properties of the substances involved and data on the geological and hydro-geological environment.
 - Use remediation methods which exclude additional environmental risks as far as possible.
 - Closely supervise the remediation with state-of-the art analytical monitoring.
 - Protect employees, contractors, passers-by and surroundings from unacceptable emissions.
 - Ensure adequate information is provided to the public and authorities.
 - Aim for long-term sustainable solutions that minimize the risk to our company and future risk to the environment.

A.2.4 Nature Conservation

- Consider nature-oriented design of the Site, allowing for wildlife habitats.
- Minimize land use and soil sealing through appropriate master planning of the Site and building design.
- Consider recharge of uncontaminated water into aquifer systems.

A.2.5 Clean Water

- Protect water bodies and groundwater from potential adverse impacts from
 - substances that will not be degraded in wastewater treatment,
 - persistent chemicals,
 - hydrocarbons, including fuels and solvents,
 - halogenated compounds (in particular solvents),
 - heavy metals,
 - insoluble contaminants,
 - unacceptable non-deactivated biological materials, particularly if they are genetically modified
 - active pharmaceutical ingredients and process intermediates
- Limit physical effects on water bodies and groundwater (e.g. thermal impacts, influence on the circulation).
- Where necessary, wastewater must be treated in a suitable wastewater treatment plant (own plant or common treatment plant with other companies or the public).
 - Ensure protection of water bodies, groundwater and soil in the event of malfunctioning or outage of the wastewater treatment plant. Ensure detection is provided for these situations.
- Ensure integrity of plants and installations (and in particular wastewater systems) and thus avoid infiltration of contaminants into the soil and groundwater.
 - Ensure early detection of failure in primary and secondary containment systems.
- Implement water conservation at your Site.
 - Reduce water consumption. Consider water collection and re-use.
 - Ensure a sustainable water supply.
 - Consider using rain water where applicable.

A.2.6 Clean Air

- Control or reduce the following air emission categories to both acceptable risk levels and local, internal compliance levels:
 - toxic substances
 - volatile organic carbon compounds (VOC)
 - ozone-depleting compounds (CFC, HCFC)
 - greenhouse gases, in particular halogenated hydrocarbons (CFC, HCFC, PFC, HFC etc.), carbon dioxide (CO₂) (Directive K6)

- nitrogen oxides (NO_x)
- sulfur dioxide (SO₂)
- dust, particulate matter
- Limit physical effects on air (e.g. heat input or extraction, misting or fogging, noise, light (disturbance of wildlife), etc.
- Ensure integrity of installations, thus avoiding contamination.
 - Ensure early detection of leaks.
 - Develop and implement systems and processes to handle situations when leaks occur.
- Where necessary treat waste air in an exhaust air treatment system.
 - Ensure air emission control in case of malfunctioning or outage of such systems. Ensure immediate detection of such situations and defined actions to remediate the situation.

A.2.7 Environmental Risk Assessment

While developing a new product, the impact on and risk for the environment must be analyzed, evaluated and assessed carefully. This analysis forms an essential part of the new product application.

- Conduct the necessary studies and establish the required data with sufficient time for internal and external review of the studies.
- Evaluate / estimate the predicted environmental concentrations and address / control potential significant impacts to receiving waters.
- Assess the resulting risk for the environment, animals and humans.
- Update the risk assessment as available information or assumptions (e.g. marketed quantities) change.

A.3 Resources

Roche products and our business processes and manufacturing practices should be designed to ensure that the best possible use is made of all resources used. Efficient use of resources also minimizes the amount of waste generated. Detailed maintenance of and attention to processes and process equipment will help to ensure that maximum efficiency is maintained.

Consumption of every resource at Roche must be well managed.

- Build awareness concerning consumption at work and at home.
- Motivate people to take steps to reduce their consumption (rewards / recognition).
- Educate, inform and consult individuals on methods and technology.

- Audit and check resource consumption to maintain focus on conservation.
- Report to management on efforts to conserve and results achieved.

The following principles and procedures in particular should be observed:

A.3.1 Energy

- Professionally manage energy production, distribution and consumption (energy management system).
 - Measure and monitor all energy flows.
 - Systematically look for energy conservation opportunities.
 - Reduce emissions from energy production, distribution and consumption by conceptual and engineering measures.
 - Use low sulfur fuels with favorable carbon dioxide coefficients, preferably those that meet Roche's definition of sustainable energy (Annex 3 to Directive K18).
 - Optimize combustion technology (e.g. to reduce NO_x emissions).
 - Encourage or require the use of energy efficiency technologies appropriate to the Site. Such technologies may include co-generation, energy recovery, optimized ventilation levels, adiabatic cooling and LED lighting.
- Optimally design new buildings, machines and processes to minimize energy consumption and to use sustainable sources of energy.
- Optimize existing buildings, machines and processes regarding energy consumption.
- Evaluate potential and feasibility (e.g. reasonable cost) of alternative energies utilizing lifecycle cost methodologies.
- Ensure uninterrupted energy supply wherever this is of importance for the operation.
- Establish and maintain an Energy Action Plan detailing specific projects to be assessed and, as appropriate, implemented.

A.3.2 Chemicals, Dangerous Goods

- Optimize the consumption of chemicals and other dangerous goods.
 - Regularly search for possible synthesis and process improvements.
 - Evaluate new technologies.
- Attempt to substitute dangerous or environmentally hazardous substances by less problematic ones.
 - Consider the full life-cycle of these materials (including production, transport, use and disposal).

- Specifically control specially regulated materials:
 - narcotics and drugs that have the potential of illegal use,
 - precursors of materials which can be used for chemical weapons,
 - biological materials which can be misused for bio-warfare or bio-terrorism,
 - environmentally hazardous substances,
 - radioactive materials.
- Recycle materials where reasonably possible.

A.3.3 Water

Clean water is vital to our business but more importantly, will become one of the most important issues that we as human beings will face in the future. It is critical that we take measures now to carefully manage this precious resource.

- Optimize the quantity of water used in all types of processes. Use technologies, processes and equipment designed to consume less water.
- Consider possibilities to capture, re-use and recycle water.
- Consider drought tolerant landscaping.

A.3.4 Packaging Materials

- Minimize the quantity of packaging materials used for all types of products and operations, without compromising safety and quality.
- Choose those packaging materials with favorable properties (eco-balance, safety, potential for re-use and recycling).
- Re-use and recycle packaging materials where possible.

A.3.5 Data on Materials

- Ensure that all necessary data on safety, security, health and environmental protection is available for all materials used. Where relevant data is missing, generate it.
- Document the data.
- Make the relevant information available for those who handle the materials, in adequate form for the different audiences.
- Label materials / containers properly.

A.3.6 Eco-efficiency, Eco-balance

In line with the risk analysis concept, determine, document, assess and if necessary and possible, reduce the environmental impact of a Site.

- When selecting one of several possible alternatives for processes, installations and projects, evaluate and consider the eco-balance in the same manner, and with the same priority, as financial, technical or capacity considerations.
- Analyze ecological measures regarding the positive effect obtained in relation to the full life-cycle cost of the measure. Those measures with the best eco-efficiency should be implemented with priority.

A.3.7 Suppliers, Service providers, Outsourcing partners, Contractors

- When selecting suppliers, service providers, outsourcing partners or contractors, consider their SHE performance, sustainability practices and integrity in addition to their financial, technical or capacity capabilities.
- The depth of the evaluations and the decision criteria depend on the nature of the proposed level of business with these partners:
 - Inherent SHE risks and problems in the supplies or services delivered
 - Specificity for our type of business vs. general types of supplies or services
 - Volume of the contract
 - Exclusivity vs. commodity
- Regularly evaluate existing suppliers, service providers, outsourcing partners and contractors regarding their SHE performance through questionnaires, and where necessary by means of audits.
- Existing suppliers, service providers, outsourcing partners and contractors who do not meet our minimum SHE requirements, must be urged to improve their performance and standards. If they don't respond in an acceptable manner, the contract should be terminated. In critical cases, this should occur immediately.
- Contracts should contain corresponding provisions (SHE agreement).

A.4 Tangible and Intangible Assets

A.4.1 Buildings

- The SHE Officer, SSO and SHE team must be involved in the project design, planning and execution from the beginning.
- Consider all SHE aspects during the conceptual and design planning stages of a project. Risk analysis is important for identifying SHE risks at very early stages.
- Optimize new buildings regarding ecology.
 - Optimize the siting of a building to maximize / minimize heating and cooling needs.
 - Use appropriate materials, including recycled material where it makes sense.
 - Carefully select the energy sources and use best available energy technology.
 - Reduce heating, cooling and ventilation to what is really necessary and use best available HVAC technology with special emphasis on heat recovery.
- Design the buildings to provide for safe, healthy and ergonomically correct work areas.
 - Fire safety and life safety should be inherent in the design.
 - Build the necessary fire protection installations and escape routes.
 - Provide ample space for work areas and utility areas.
 - Ensure proper workplace lighting, view and ergonomic fit of equipment.
 - Keep noise levels in the workplace to comfortable levels and consider noise contribution when purchasing equipment.
 - Provide the necessary heating, cooling and ventilation – optimizing for health and environmental protection.
- Design security into the building and into the processes to be performed.
 - Ensure access control.
 - Protect assets against theft and espionage (physical assets and information).
 - Protect against intrusion (sabotage or similar attacks).
 - Install the necessary monitoring and communication systems.
 - Organize appropriate emergency response.
- When deciding on the location for a building, consider SHE topics such as:
 - Access (e.g. public transportation)
 - Natural disasters (earthquakes, flooding, landslides, and storms)
 - Availability and easy transport of resources

- Heating, cooling and ventilation needs
- Security situation, etc.

A.4.2 Plants and Installations, Infrastructure

- Design plants and installations for healthy and safe operation.
 - Design for inherently safe technologies (containment vs. relief, passive vs. active, etc.).
 - Perform risk analyses at multiple points in the design and planning process and implement the identified risk reduction measures.
 - Build the necessary safety equipment (alarms, automatic shut-down, release installation etc.).
 - Design and build the plants and installations in a way that workers are protected from contact with production materials. Include technical control measures to protect against exposures and their physical effects and do not rely primarily upon personal protective equipment (PPE) to control hazardous exposures.
 - Construct plants and installations in a way that they can be operated and maintained in a simple and safe way, and not by primarily relying on worker behavior.
 - Design and construct plants and installations in a way that effects of natural disasters (earthquakes, flooding, landslides, and storms) are limited.
- Design, construct, deploy and maintain IT systems for high reliability. Where critical systems and processes depend on IT systems, specifically secure these systems (e.g. uninterrupted power supply; access control; self-diagnosing capability, alarms).
- Provide clear and comprehensive standard operating procedures and instruction manuals.
- Maintain plant equipment in good working order and conduct repairs in a timely and professional manner.
 - Ensure good housekeeping.
 - Organize and implement a preventive maintenance program.

A.4.3 Raw Materials, Excipients, Products, and Packaging Material

- Plan for, provide and ensure safe, secure and environmentally sensitive storage of these materials.
 - Ensure the necessary safety measures according to the inherent hazards associated with the materials (classification).
 - Separate non-compatible materials.
 - Construct warehouses for minimal heating and cooling.
 - Ensure containment of powders, liquids and gases in the event of an incident.
- Optimize transport of all materials – and especially those classified as dangerous goods – for sustainability, in particular safety and ecology.
 - Avoid unnecessary transport.
 - Optimize packaging for sustainability.
 - Consider selecting the most ecological transport means and routes.
 - Ensure full compliance with transport regulations.
 - Verify that only contract transport and warehousing service providers with a good SHE level are utilized.
- Enable the safe use of our diagnostic instruments and systems through
 - a construction which is optimized for safe operation, maintenance and disposal
 - clear and comprehensive safety instructions in the instrument manual.

A.4.4 Residual Materials, Waste

- Initiate a process that generates waste only after determining an acceptable method of re-using, recycling or disposing of the waste.
- Treat waste and residual materials using the following prioritization methodology (from most preferred to least preferred):
 - Recycle to the original starting material, as far as technically, ecologically (in terms of energy expenditure and generation of further waste) and economically feasible.
 - Down-cycle to a lower-value product (e.g. paper to cardboard).
 - Valorize, i.e. process to a saleable product.
 - Thermally valorize, i.e. incinerate with heat recovery (for waste with a high energy content, e.g. distillation residues, inseparable solvent mixtures etc.).
 - Incinerate without heat recovery, i.e. conversion to a mineralized end product.
 - Landfill (for restrictions see below).

- Collect all waste and residual materials.
 - Identify all wastes and residual materials
 - Separate the materials to assist in their further use or in optimizing waste disposal. Avoid mixing of waste.
 - Pre-treat waste (including used diagnostic instruments) which might form dangerous decomposition products in the disposal process or which might otherwise harm people engaged in handling and treating the waste.
 - Safely store and transport wastes according to their hazards.
 - Document type, quality and quantity of all wastes and residual materials and the pathway of their disposal. Ensure compliance with all local regulatory and Roche provisions regarding such documentation.
 - Ensure safekeeping of this documentation for an unlimited period.
- Re-use or recycle wastes and residual material whenever possible and sensible.
 - Consider selling these materials as raw materials or for energy recovery.
 - If not re-used or recycled internally, ensure that you select an outside partner who operates on an acceptable SHE level. Verify this by audit.
 - Ensure proper transport of the waste materials, in full compliance with the regulations in this field.
- Dispose of all other wastes and residual materials in a safe and ecologically friendly manner.
 - Do not landfill chemical waste or any hazardous materials.
 - Minimize landfilling of other waste (other than inert materials like building rubble or slag).
 - Consider incineration of all combustible materials. Ensure that combustion plants used operate at a high technical and environmental standard.
 - Carefully select disposal services which operate at an acceptable SHE level. Verify this by audit.
 - Ensure proper transport of the waste materials, in full compliance with the regulations in this field.
 - Ensure full documentation of the disposal of your materials and maintain this documentation in an accessible manner.
 - Strictly follow the local regulatory requirements as they may differ considerably from country to country.

A.4.5 Car fleet

- When procuring vehicles for Roche business use, they should be:
 - suitable for their intended purpose (carriage of tools, equipment or materials),
 - have among the highest safety ratings possible and are equipped with available and functional state-of-the-art safety features including, but not limited to, seat belts for all passengers and head restraints on all seats whenever possible,
 - selected for ergonomic considerations (e.g., fully adjustable driver's seat, trunk/boot depth and lift over height for safe loading and unloading of equipment and material),
 - fuel efficient, as per Group Directive K18 and its Annex 2, which is updated and strengthened periodically.
- Consider having company cars instead of paying employees for using their private cars, because this way we have more direct influence on car selection.
- Train all employees who drive cars for business purposes in safe driving.

A.4.6 Knowledge, Know-how

Take all necessary measures to protect intellectual property and critical knowledge and know-how. For more details see the Roche Group *Code of Conduct* (<http://we.intranet.roche.com/sites/Roche/content/about-roche/directives-and-guidelines/Roche-Group-Code-of-Conduct/Pages/default.aspx>; and the guidelines and directives listed there).

Intellectual property is the basis of all our business. It must be protected accordingly.

- Physical protection of corresponding information (buildings, offices, office cupboard, data centers)
- Education of employees regarding communication on protected information (verbal at conferences, in the private area, while travelling; e-mails; social media; web pages; cloud computing / cloud storage; publications; etc.)
- IT security (managed by IT)

A.5 Processes

Carefully document all technical, business and other processes which have relevant SHE elements.

- Define the prerequisites for starting the process.
- When changing a process, ensure, by a thorough analysis that the prerequisites are still met.
- Periodically verify that the prerequisites are still met.
- Continuously improve the SHE performance in all processes.
- Make all process specific SHE information and instructions readily available for line employees, e.g. by providing this information in the standard operating procedures (SOPs) and work instructions.

Put into force by Group SHE on January 1, 2019