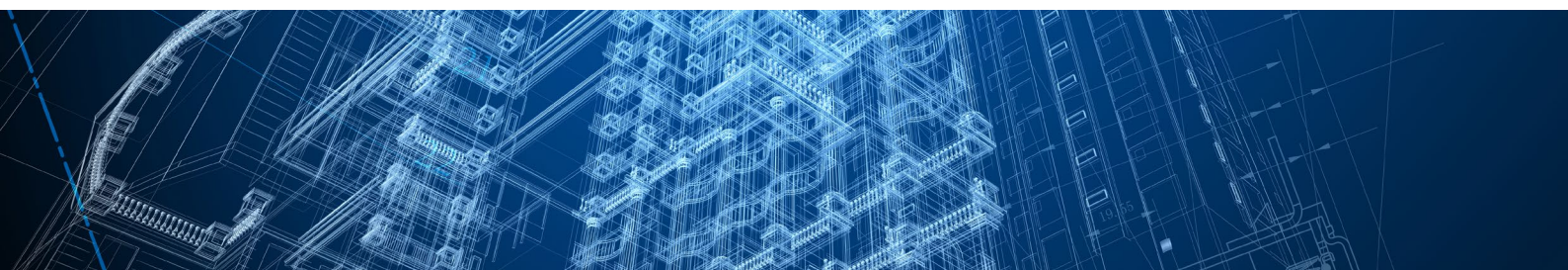


PAS 440:2020

Responsible innovation – Guide



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Contents

Preface	ii
Foreword	iii
Introduction.....	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Principles relevant to responsible innovation	3
5 PAS 440 overall structure and implementation	5
6 Company-level responsibility: organizational behaviour	7
7 Innovation-specific responsibility – baseline assessment	10
8 Innovation-specific responsibility – iteration and updating	16
9 Overall report	21
Annexes	
Annex A (informative) Questions to ask about benefits and risks	22
Bibliography	23
List of figures	
Figure 1 – UN Sustainable Development Goals.....	8
List of tables	
Table 1 – Demonstrating company-level social responsibility	9
Table 2 – Responsible Innovation Framework (RIF)	11
Table 3 – Responsible engagement guidelines	19

Preface

We have all heard someone playing a musical instrument out of tune. It sounds pretty unpleasant. When two people play together, and they are not properly in tune, it sounds even worse. The more people playing, and the further separated their tuning is, the worse it gets. A large modern orchestra can consist of over 100 musicians, depending upon the piece they are playing. That many people playing out of tune would sound truly awful which is why, before concerts, we hear them honing their tuning to be perfect. It is customary that everyone tunes to the note A (above middle C) played on the oboe. The frequency of the note the oboe plays, concert pitch, is 440 Hertz. Only when everyone's playing is rooted to the same tuning note (usually 440 Hz) does it sound good.

This is the inspiration for the number of this Publicly Available Specification (or PAS) on responsible innovation. Just as the different sections and instruments in an orchestra only play beautifully together when they are tuned to the same note, so too is innovation more successful when the different stakeholders in a value chain act in an agreed and coherent way. New products, services and processes that work for all parts of a supply chain, and are accepted by wider society, have the potential to flourish. They are well positioned to serve the interests of companies, suppliers and customers and citizens. Where these conditions do not apply then the new products, services and processes are more vulnerable, and far more likely to fail.

In his Nature Paper of 1880 (ELLIS, A. *The History of Musical Pitch*. *Nature* 21, 550–554, (1880)) Alexander J Ellis described more than 30 different pitch systems in use across Europe during the 18th and 19th centuries. Similarly, when we look at responsible innovation today, we find a large number of different approaches being adopted by different organisations, working in different technology and industry areas, with different stakeholders and societal expectations. Before the creation of PAS 440 there was no single overarching point of reference for innovators wishing to develop their new products, services or processes in a responsible manner.

It is hoped that PAS 440 might simplify and bring coherence to the area of responsible innovation. It provides guidance and help to innovators and stakeholders on how innovation can best be taken forward.

We are keen to track how well it does this. For this reason we are making it available at no charge, but would ask that companies using it share their experiences of doing so with us, so that we can improve future versions of the document and inform future programmes in specific innovation areas. If you are reading this introduction, this might well apply to you. Please reach out to us on PAS440@innovateuk.ukri.org providing your contact details so we can, at the appropriate review point, send you a user survey and keep you up to date with future standards developments.

Thank you for innovating responsibly.

Paul Mason
Director of Responsive Programmes
Innovate UK

Foreword

This PAS was sponsored by Innovate UK. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 March 2020.

Acknowledgement is given to Joyce Tait of the Innogen Institute, University of Edinburgh, as the Technical Author of this PAS and to Paul Mason, of Innovate UK for his contribution to the drafting of the PAS, and to the following organizations that were involved in the development of this PAS as members of the steering group:

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- Knight Design Innovation Limited
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Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

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This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a guide to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

As a guide, this PAS takes the form of guidance and recommendations. It should not be quoted as if it were a specification or a code of practice and claims of compliance cannot be made to it.

Presentational conventions

The guidance in this standard is presented in roman (i.e. upright) type. Any recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Introduction

Companies are increasingly facing demands that their products, processes, services and business models are developed responsibly. However, these demands are likely to vary depending on the nature of the innovations involved, the anticipated benefits and risks, and where they accrue. PAS 440 will help innovators to work through the demands of innovating in a responsible manner and to demonstrate their responsible behaviour to interested stakeholders. It is a practical guide that adds value to the innovation process and helps to improve the robustness with which potential problems can be addressed. It also attempts to be realistic about the demands on company resources (time and money) in often fiercely competitive environments.

Different challenges can arise at different stages in developing innovation, and societal attitudes to, and demands for, specific innovations evolve over time. PAS 440 particularly addresses the needs of companies developing transformative innovations that can lead to:

- the creation of new modes of production and new markets;
- sectoral transformations and the displacement of incumbent products or even companies; and
- the creation of entirely new sectors with significant societal and economic benefits.

At the early stages of development of these innovations, there might not be an existing regulatory system to guide the innovator or a pre-existing business model to be followed. Alternatively there might be a need to create a new value chain or a new role for a company in an existing value chain. This PAS is also helpful in the case of some incremental innovations, where the innovation landscape is mature, where new processes or other changes are being considered, or new markets are being opened up, particularly where they attract the interest and attention of members of the public.

PAS 440 is thus relevant where significantly new types of innovation are being undertaken. This could be in any market, for example, healthcare, transport, financial services, construction, aerospace, and agriculture/food production, and based on new developments in any technology including, but not limited to, artificial intelligence (AI), big data, robotics, materials sciences, photonics, biotechnology, sensors, electronics, physics or chemistry. It is intended to help

companies to manage the process of responsible innovation across all development stages up to and beyond market launch and gives guidance on charting a path through the potentially conflicting aspirations and demands of a broad range of different stakeholders.

Following the guidelines in PAS 440 can lead to additional benefits for the company, including, depending on the specific circumstances:

- long-term cost and risk reductions;
- more resilient new product/service offerings to potential customers;
- improvement of societal trust in the company and maintenance of social license to operate;
- improved relations with investors and greater investor confidence in the company;
- greater attractiveness as an employer;
- better supply chain relationships;
- improved reputation and brand value;
- increased innovation capabilities;
- improved ability to communicate the value of products and services to investors, companies, customers and citizens;
- better relationships with governments, regulators and local communities; and
- improved capacity for long term planning and sustainability.

PAS 440 has been designed to minimize the associated costs of compliance for companies and the above benefits would be expected to outweigh these costs, particularly taking account of the avoided costs of any mistakes. It supports companies in demonstrating that they are innovating responsibly whilst taking account of their needs to continue to innovate in a timely manner and to ensure that they remain competitive internationally. Responsible companies can therefore anticipate delivery of the positive results of their innovations while minimizing unintended or unforeseen negative consequences.

Responsible innovation (RI) also contributes to the Europe 2020 Strategy on the creation of “a smarter, greener economy where our prosperity will come from research and innovation ... [and] research and innovation must respond to the needs and ambitions of society, reflect its values and be responsible” [1].

1 Scope

This PAS provides guidance for companies that wish to innovate responsibly and to demonstrate their responsible behaviour by helping them to structure their thinking and by guiding their actions.

This PAS is relevant to all those taking new products, services or processes to market, and is also of interest to a company's wider stakeholders including: members of the public, customers, scientists/innovators, regulators/policy makers, financiers and investors, suppliers, current and prospective employees, and collaborators.

There are two main elements of responsible behaviour by companies:

- a) company-level responsibility, applying to organizational behaviour in general (Clause 6); and
- b) innovation-level responsibility, specific to each innovative development or class of developments (Clauses 7 and 8).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this PAS, the following terms and definitions apply.

3.1 balance

weighting the relative importance or salience of differently-held perspectives, making clear the reasons behind the resulting decision

NOTE *Balancing is employed where there is vagueness, conflict or disagreement among ethical principles, interests and/or values.*

3.2 business model

rationale for how a business creates, captures and delivers value

NOTE *As business sectors evolve, recognizable and codifiable business models emerge and become the template upon which new market entrants can model their future business and competition strategies.*

3.3 governance

process, centralized or decentralized, of providing oversight over the way that a company, organization, institution or system is managed, by internal groups or external entities and authorities

NOTE 1 *It includes questions such as: who has power?, who makes decisions?, how do other players make their voices heard? and how is account rendered?*

NOTE 2 *For responsible innovation, 'governance' includes:*

- a) *the regulatory systems set up to control risks to people and the environment arising from innovative developments;*
- b) *the guidelines and standards related to regulatory systems; and*
- c) *stakeholder engagement.*

3.4 innovation

implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations

NOTE 1 *See <https://stats.oecd.org/glossary/detail.asp?ID=6865>*

NOTE 2 *Innovations incorporate different degrees of novelty (see ISO DIS 56000, 3.2.1), ranging from:*

- a) *those that are path-breaking, creating step changes in existing business models and value chains, involving new markets and networks and/or radical changes to components of existing value chains (e.g. digital photography displacing 35 mm film or a shift from petrochemicals-based to fermentation-based manufacture of high-value chemicals) (referred to in this PAS as transformative innovations); to*
- b) *those that involve more incremental changes, that fit well within existing business models and value chains (referred to in this PAS as incremental innovations).*

3.5 responsible innovation

careful consideration of, and action to address, the potential impacts of introducing a new product, service, process or business model

NOTE *It considers the benefits that are derived from an innovation and seeks to eliminate, minimize or mitigate any potential downsides from the perspectives of the company, its employees, suppliers and customers, and stakeholders who might be impacted, directly or indirectly, by the innovation. It is an attempt to improve our collective futures by taking responsibility for, and improving, today's innovation practices.*

3.6 regulation

act of legally enforceable rule-making by a government or other authority in order to control the way something is done or the way people behave

3.7 stakeholder (for an organization)

any group or individual that has an interest in any decision or activity of an organization

NOTE *See ISO 26000.*

3.8 value chain

how value, however it is measured, is distributed along a supply chain through interactions and transactions between companies with a variety of different business models covering the full range of activities required to bring a product to market and end use, including where appropriate, disposal and recycling

4 Principles relevant to responsible innovation

4.1 General

Companies innovating in a responsible manner need, at the same time, to raise financial investment, meet the requirements of customers and relevant regulations and scope the demands of existing markets or create entirely new markets. In some cases, they may also need to devise new business models and orchestrate the emergence of new value chains involving collaborating companies each contributing to a complex end-product. Reconciling these needs with the requirements of RI can be challenging for a company and adoption of a set of basic principles can support decision making, particularly where there are multiple stakeholder interests and values.

4.2 Principles relevant to the company as a whole (Clause 6)

Many companies have already gone down the route of specifying the ethical and social responsibility principles that they are committed to observing, as part of their basic corporate governance. Where a company has not already decided on the principles relevant to its sector and operations, there are numerous precedents that can be followed. To give just one example, the BS ISO 26000 specifies the following ethical principles:

- a) accountability for impacts on society, the environment and the economy;
- b) transparency in decisions that impact on society and the environment;
- c) ethical behaviour;
- d) respect for stakeholder interests;
- e) respect for the rule of law;
- f) respect for international norms of behaviour; and
- g) respect for human rights.

4.3 Principles relevant to the development of specific innovations (Clauses 7 and 8)

The following principles are applied in this PAS to specific innovations, building on recent developments and current practice in national and international governance of innovation, and are relevant to the behaviour of policy makers and regulators as much as to innovators in companies. It is important for innovators to understand what they should expect from regulators and policy makers, and also to be aware of how these principles might relate to the perspectives of stakeholders.

The **Precautionary Principle** is widely invoked in situations where there is uncertainty about future benefits and risks of an innovation, particularly potential impacts on human health and well-being or the environment. It is incorporated, through the Treaty of Rome, in European approaches to risk mitigation and the governance of innovation. *The European Commission (EC) Communication on the Precautionary Principle* [2] specifies how it should be applied, including where there are potentially dangerous effects in the absence of "sufficient certainty" about the impacts.

The EC Communication is intended to ensure a balanced interpretation of the precautionary principle and recommends that, where action is deemed necessary, measures based on the precautionary principle should be:

- a) proportional to the chosen level of protection (meaning "tailoring measures to the chosen level of protection";
- b) non-discriminatory in their application;
- c) consistent with similar measures already taken;
- d) based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis);
- e) subject to review, in the light of new scientific data; and
- f) capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The **Innovation Principle** [3, 4] is a more recent European initiative stimulated in part by the perceived failure of many EU policies and regulatory decisions to implement the precautionary principle in a proportionate way. It focuses on innovation as a driver for jobs and growth and its contribution to meeting important societal needs. It states that whenever policy is developed, the impact on innovation should be fully assessed and that the choice and design of regulatory tools should consider the benefits of innovation among other considerations. It is thus intended to be a complementary, balancing principle to the Precautionary Principle, recognizing the need to protect society and the environment while also safeguarding a nation's ability to innovate. Innovation will be needed to meet the challenges raised by, for example, climate change, antimicrobial resistance, hunger and food shortages, and biodiversity loss, along with impacts on institutions, societal behaviour and other societal implications. Where an innovation has the ability to meet such challenges, and if it can do so sustainably and in compliance with ethical requirements such as those specified in BS ISO 26000 and in this PAS, then the Nuffield Council Report on *Biofuels: ethical issues* [5] recommends that a company should be encouraged to innovate, as long as the investment will be financially attractive.

Both the Precautionary Principle and the Innovation Principle refer to the associated principles of **Proportionality and Adaptation** [3, 4, 6]. Under the EU principle of proportionality, actions should be limited to what is necessary to achieve the objectives of (in that case) the EU Treaties so that the content and form of the action should be in keeping with the aim pursued. In the context of this PAS, it requires that regulatory and policy actors do not go beyond what is necessary to achieve given objectives, and that protecting society from potential harm should where possible avoid stifling beneficial innovation. It also recognizes that, in a fast-changing innovation environment, regulation, guidelines and public policies need to adapt to the evolving properties of an innovation during its development and subsequently in use, the **Adaptation Principle**.

4.4 The need for balance in the implementation of principles

Having a set of principles does not provide simple answers to the potential dilemmas around decisions about responsible innovation. The choices favoured by the adoption of one principle can often conflict with the choices favoured by another. The concept of balance can be used as a means to resolve conflicts and to justify choices made in the development of innovations.

***NOTE** For example finding a middle way between opposing views, or a compromise across a range of different stakeholder positions, may be preferable for the majority of stakeholders to adopting one contested position.*

Given the range of potential ethical principles and issues of concern put forward by different stakeholder groups, an important element of responsible innovation is to find a balance:

- across the interests and values of different stakeholder groups;
- between the precautionary principle and the innovation principle; and
- between the benefits and risks of an innovation and where they accrue.

This is therefore about balancing the benefits that a particular innovation can bring with any potential downsides that might exist across the broad range of perspectives that are likely to be encountered among different stakeholders (see Clause 8).

5 PAS 440 overall structure and implementation

5.1 The governance context

Citizens expect their governments to work to enhance their standard of living and to protect them from harm, and so governments play a key role in creating an environment that encourages the development of life enhancing products and services, and ensuring the safety of the citizen and the environment. Likewise, a company's Board will have well established control processes and fiduciary duties. Given that innovation is an inherently uncertain activity that comes with a risk of failure, it may already be on the company's risk register, and compliance with this PAS could help the Board to better manage risk within the company.

Where the organization already has an ethics committee they should be involved in the RI process. Alternatively, the process of embedding RI within the organization could be a stimulus to appoint an ethics committee, where this is deemed appropriate.

This PAS takes account of:

- a) formal regulation;
- b) standards and guidelines; and
- c) RI.

In guiding a company to meet its responsibilities to society and to stakeholders, the principles of precaution, innovation, proportionality and adaptation, are equally applicable to the development of regulatory systems and to the responsibility dimension of a company's behaviour (Clause 4) [7]. Considering regulation and RI together, as inter-connected components of the development of an innovation, can make it easier to comply with both components.

Where an innovation is transformative or the subject of societal attention for any other reason, stakeholder engagement undertaken as part of RI can also inform government bodies and regulators on the future development of policies and regulations. A well-executed and documented RI approach can therefore form a useful part of a company's evidence used in conversation with regulators and policy makers, as part of a broader evidence gathering approach, in developing future regulatory systems.

5.2 Making RI manageable for innovating companies

This PAS is intended to support a company's need to:

- a) act in a manner that is demonstrably reasonable and fair;
- b) generate trust among stakeholders in governance and regulatory processes;
- c) build on procedures that are already familiar to many companies, such as compliance with a social responsibility standard and using a risk assessment matrix as part of conventional project management;
- d) allow early consideration of issues and implications associated with the development of innovations; and
- e) be cost-effective.

Companies undertaking stakeholder engagement on innovations can face significant challenges in dealing with the expectations of some advocacy groups, particularly those with strong views about specific developments or classes of development. Table 3 includes responsible engagement guidelines as a balanced, equitable approach relevant to these circumstances.

5.3 Basic elements of the RI approach

This PAS includes the following elements:

a) **Company-level responsibility applying to organizational behaviour in general**

Compliance with a company-level social responsibility standard, observing basic ethical principles, is a useful starting point for RI and for many companies it may already be part of their standard operating procedures (Clause 6). Where a company has not previously committed to such a company-level standard, applying it in the context of one particular innovation could be a good first step towards its more general adoption.

Given the need to make the RI process manageable for companies, this PAS proposes that, where innovations are incremental and do not have any properties that would justify innovation-specific consideration, compliance with a company-level social responsibility standard might be sufficient to give assurance that innovation is being conducted responsibly.

b) Innovation-specific responsibility, applying to each innovative development or class of developments

For transformative innovations or where an incremental innovation attracts strong public interest, potentially leading to controversy: the innovation-level RI framework and guidelines described in Clauses 7 and 8 should be adopted. This approach meets the principles described in Clause 4 and helps a company to understand:

- 1) what is (and is not) required of them for different innovations at different stages in the development process; and
- 2) how to document the outcomes of their responsible innovation approach in a way that meets stakeholder and societal expectations.

c) RI report

Clause 9 outlines what should be included in an overall report covering the social responsibility approach of the company as a whole, as it is applied to innovation as a generic activity, and to each innovation or group of innovations being developed by the company.

In addition, since investors are increasingly interested in the ethical positions of their invested companies, a company could consider beginning to undertake a RI assessment before starting major funding raising activities.

If developing a responsible innovation approach is new to a company, it could start by doing an audit for a previous innovation, potentially learning some lessons and thinking about what might have been done differently. The company could also consider:

- 1) whether there are any innovations where it would be useful to audit responsibility in their ongoing delivery in the market place; or
- 2) whether it should begin an RI assessment process for any potentially transformative innovations that are currently part-way through the development process.

The next step would be to think about plans for future innovations and how they can be captured.

5.4 Timing and scale of adoption of a RI approach

Demonstrating responsible corporate behaviour is an essential background process, underlying any further consideration of responsibility in relation to specific innovations, and it might be part of the company's on-going general reporting structure. For incremental innovations where the company decides that further innovation-specific scrutiny is not necessary, explaining its approach to social responsibility as part of its routine reporting structure, and its justification for not undertaking innovation-specific RI requirements, should be sufficient assurance of responsible behaviour (Clause 9).

For transformative, and relevant incremental, innovations, companies should begin to implement the RI approach described in Clauses 7 and 8 when the direction of travel for the proposed innovation is clear, but before the implementation detail is locked down. This advice is an attempt to balance:

- a) the need of companies to avoid spending time considering issues that will turn out not to be relevant to the innovation as finally specified; against
- b) the possibility that early reflection about the positive and negative impacts of an innovation can lead to useful modifications of its properties.

6 Company-level responsibility: organizational behaviour

6.1 General

A company cannot claim to be innovating responsibly if it does not follow the accepted norms of national and international good conduct, often referred to as its “social responsibility”. Corporate social responsibility (CSR) is rapidly becoming a routine component of business self-regulation, subject to societal pressures to demonstrate that it is not just “window dressing” or “green-washing”. Many, particularly larger, companies already produce externally audited reports that cover sustainable development and social responsibility issues.

NOTE 1 For example, *Triple Bottom Line reports* covering “people, planet and profit”.

NOTE 2 A number of reporting schemes have been set up to help companies to demonstrate social responsibility, e.g. *BS ISO 26000*.

To give assurance of responsible development of individual innovations, all companies should first demonstrate that they meet basic social responsibility expectations.

This Clause lays out the aspects of overall company behaviour that individuals, stakeholders and society are likely to care about. The aim is to reinforce positive company behaviours, the kinds of thing that they would be applauded for achieving, and to discourage behaviours that would be regarded as negative and detrimental to society, the environment and/or human health and well-being. This PAS has not specified an ideal list of responsible company behaviours, but it suggests here how responsible company behaviour, as a foundation for responsible innovation, could be demonstrated, the kinds of issues that might usefully be considered, and where additional information can be found.

6.2 Relevant organization-level standards and goals

Stakeholders, including members of the public in general, increasingly expect companies to meet basic requirements for responsible behaviour as an integral part of their standard operating procedures. The assumption for this PAS is that, if a company has not already made a commitment to this level of responsible background behaviour, it might be willing to begin to consider it, at least in the context of any transformative or other innovation of concern to stakeholders that

they might be developing. These organization-level commitments, if adopted, should be embedded in the standard operating procedures of the company to create a firm foundation for incremental innovations (this Clause) and transformative innovations (Clauses 7 and 8). There is a risk for companies that if they fail to meet these expectations the cost, in time and money, will far exceed that of meeting the social responsibility criteria.

Responsible, ethical company behaviour is becoming a regular topic of discussion in news media and there are now many sets of social responsibility guidelines developed by standards bodies, consultancies and industry organizations for the sectors they serve. They describe criteria for responsible company behaviour or, conversely, draw attention to what would be regarded as irresponsible behaviour. They are also a useful source of inspiration for a company wanting to understand better the issues that its stakeholders are likely to be interested in, to demonstrate organizational level responsibility and to articulate their potential positive contributions to the wider societal and environmental landscape.

One example of a formal standard, BS ISO 26000, covers the following norms of national and international good conduct by a company, as noted in 4.2:

- a) accountability for its impacts on society, the environment and the economy;
- b) transparency in its decisions that impact on society and the environment;
- c) ethical behaviour;
- d) respect for stakeholder interests;
- e) respect for the rule of law;
- f) respect for international norms of behaviour; and
- g) respect for human rights.

BS ISO 26000 also meets the requirements of the European Commission’s position statement on responsible research and innovation [1] related to engagement, gender equality, science education, open access, ethics, and governance.

Serving a different function from that of a standard, the seventeen *UN Sustainable Development Goals* (SDGs) [8] (see Figure 1) codify a set of societal aspirations that can be used as a resource for any

company that wants to develop a better understanding of societal and stakeholder interests and values relevant to how they conduct their business. Whilst not exclusively so, the following six SDGs are probably the most relevant to demonstrating social responsibility at the organization/company level relevant to this Clause. (The others are more relevant to specific innovations as discussed in Clauses 7 and 8.)

The web link for each goal leads to a detailed explanation of the issue and how it can be addressed. The number in each case is that of the specific SDG in Figure 1.

- 1) Ensure inclusive and equitable quality education and promote lifelong learning¹⁾ (4);
- 2) Achieve gender equality and empower all women and girls²⁾ (5);
- 3) Promote inclusive and sustainable economic growth, employment and decent work for all³⁾ (8);
- 4) Reduce inequalities within and among countries⁴⁾ (10);
- 5) Promote just, peaceful and inclusive societies⁵⁾ (16);
- 6) Strengthen the means of implementation and revitalise the global partnership for sustainable development⁶⁾ (17).

6.3 Demonstrating company-level compliance – Social responsibility report

It is important for a company, not just to reassure itself that its overall behaviour is responsible, but to demonstrate this clearly to stakeholders, e.g. through a publicly available report, preferably based on a recognized authoritative set of guidelines such as BS ISO 26000. Alternatively, Table 1 along with an associated report, updated on a regular basis (see Clause 9), can be used to demonstrate responsible behaviour at the company level for the purposes of this PAS. It should cover the responsibility elements that are relevant at the company level and how the company assures compliance with its responsibilities, currently and in future.

- a) The overall report should describe how the items to be included in Column 1 of Table 1 were decided, e.g. by company staff and approved by senior managers.
- b) Column 2 should summarize what the company currently does to assure itself that it is behaving responsibly in each area identified as relevant to it.
- c) Column 3 (where necessary) should note any improvements needed and describe how these will be addressed.

Figure 1 – UN Sustainable Development Goals



¹⁾ <https://sustainabledevelopment.un.org/sdg4>

²⁾ <https://www.un.org/sustainabledevelopment/gender-equality/>

³⁾ <https://www.un.org/sustainabledevelopment/economic-growth/>

⁴⁾ <https://www.un.org/sustainabledevelopment/inequality/>

⁵⁾ <https://www.un.org/sustainabledevelopment/peace-justice/>

⁶⁾ <https://sustainabledevelopment.un.org/sdg17>

If there is no company commitment to a social responsibility standard, the company should expect that the table and the report will be updated regularly, based on comments from staff and (potentially) from stakeholders, leading over time to a more robust document.

Demonstrating responsible organizational behaviour is just as important for a start-up or a small or medium-sized company as it is for a multinational, and equally beneficial, but the amount of effort required has to be proportionate to the company's size.

Also, most companies work with a range of other companies and organizations in sometimes complex value chains and they will have an interest in ensuring that their collaborators also behave responsibly (see 7.3, value chain elements).

Where a company is mainly undertaking incremental innovation, meeting the above requirements may be sufficient to demonstrate that they are behaving responsibly, although companies should bear in mind that a succession of incremental innovations can lead to transformative outcomes, requiring an innovation-specific consideration of RI. Most incremental innovations might not make a big difference to the company's organization-level commitments to responsible behaviour. Companies are expected to make a judgement, based on their own internal circumstances and broader understanding of stakeholder perspectives, on where to draw this boundary between innovations that are significant enough to warrant an innovation-specific Responsible Innovation Framework (RIF) (see Clause 7), and those where the company can rely on corporate-level assurances. In doing this the principles outlined in Clause 4 and the overall guidelines on implementing RI in Clause 5 are relevant.

If any innovations are expected to have a significant impact on organization-level responsibility criteria as described in this clause, or to have significant implications, positive or negative, for the criteria discussed in Clauses 7 and 8, the company would also be expected to meet these innovation-specific requirements.

Table 1 – Demonstrating company-level social responsibility

Table Heading <i>Company name:</i> <i>Sector of operation:</i> <i>Geographic location of operations:</i> <i>Date:</i> <i>Authorized company contact:</i>		
Element of responsible organization-level behaviour	Evidence of company's contribution	Aspirations for future improvement (if necessary)
List to be based on BS ISO 26000 criteria, relevant elements of the SDGs, or other sources	E.g. the company's annual report or other formal documents.	Identify any areas where performance is not optimal and note any plans for improvement

7 Innovation-specific responsibility – baseline assessment

7.1 General

Beyond the organization-level social responsibility described in Clause 6, Clauses 7 and 8 deal with innovation-specific requirements relevant to transformative innovations or those that are incremental but are likely to be of particular interest to stakeholders or to wider society.

The RIF focuses on the properties of the innovation, its benefits and risks, and the perspectives, needs and desires of stakeholders. It is relevant to transformative innovations (new products, processes, services or business models) and some incremental innovations that can lead to significant changes in a company's portfolio or attract the interest and possible concerns of members of the public. Applied iteratively, the RIF covers issues that are relevant to RI and changes made to products, processes or services during development or after market launch and any mitigating steps undertaken with regard to risks. It provides guidance for responsibly creating new products, processes or services, where an innovation is likely to be transformative of existing business models or value chains, where regulatory systems have not yet been formalized or where there is expected to be strong public interest or divergent public opinions.

The RIF guides the company in deciding what aspects of an innovation can be relevant to demonstrating responsibility, how to reassure themselves that they are behaving responsibly as a company, and how to involve stakeholders and to demonstrate responsible behaviour to them and to the wider community. Clause 7 describes the process of setting up the first, baseline assessment of the innovation using the RIF and Clause 8 describes how subsequent iterations should be carried out as the innovation progresses through later stages of development.

Where a company is involved in several different transformative innovations, a separate RIF and related company procedures should be set up for each identifiably different innovation or class of innovations. The decision on separate treatment will depend, for example, on the degree of similarity of the technology or process involved and/or of the target markets.

7.2 The RIF template (Table 2)

The RIF template may be familiar to any company that uses a risk assessment matrix as part of its routine project management. The Framework should be updated on a regular basis, so that sequential iterations provide a record of company RI activities up to, and beyond, market launch. In many cases it may be appropriate to continue monitoring and recording positive and negative responsibility-related impacts after the innovation becomes available on the market. The reasons for the decision on whether or not to continue monitoring beyond market launch should be recorded in the overall RI Report (Clause 9).

The RIF Assessment Heading, above the Framework, should state:

- a) a reference number to identify the specific innovation(s), followed by a version number to track sequential iterations of the RIF for that innovation as it progresses through the development process;
- b) an overall vision for the innovation, including a description, targets and expected success measures;
- c) the responsible person or role within the company for this RIF at this stage of development, along with contact details, noting that the responsible person can change as the innovation progresses through phases of development.
- d) the stage of development of the innovation (e.g. "early, middle, late stage", or an alternative that fits with the company's procedures);
- e) the date of completion of that version of the RIF; and
- f) the dates of completion of previous versions of the RIF.

This PAS is intended to be used by companies from a very broad range of industry sectors with different innovation processes, properties and uses. The challenges will be different, for example, for innovative biotechnologies in a heavily regulated sector where the development process can take 10 to 15 years, compared to digital technologies which are fast-moving, agile and lean. The choice of person or role to be in charge of the RIF Assessment could be either the product or project manager, or those with more intimate knowledge of the innovation itself, depending on these innovation-specific differences.

This Clause deals with the baseline version of the RIF that identifies responsibility-related elements relevant to the innovation (RIF, Column 2), and begins to identify the stakeholders that will be relevant to these elements (RIF, Column 4). It is difficult to provide a checklist of all the issues/elements that companies should pay attention to, given the variety of innovations targeted

by this PAS, but this Clause and Clause 8 give guidance on how to identify relevant elements to be addressed, stakeholders to be involved, and how to manage the responsible innovation process.

The headings in the RIF draw attention to and support codification of the elements of responsible innovation that companies should take into account.

Table 2 – Responsible Innovation Framework (RIF)

RIF Assessment Heading: Reference number/iteration number: Innovation vision, description, targets and success measures: Named responsible person or role (contact details): Stage of development (early, middle, late): Date of completion of this version: Dates of completion of all previous versions of the RIF for this development:				
1. ID #	2. Elements of RI – identify positive and negative outcomes of the innovation(s) (see 7.3)	3. Record the reasons for inclusion of the element in the baseline assessment (see 7.3) and note any changes to elements since the previous iteration of the RIF (see 8.2)	4. Identify (see 7.4) and engage with (see 8.3) stakeholders	5. Take action (see 7.5 and 8.4)
1.x	Societal elements (benefits)			
2.x	Societal elements (risks)			
3.x	Environmental elements (benefits)			
4.x	Environmental elements (risks)			
5.x	Health-related elements (benefits)			
6.x	Health-related elements (risks)			
7.x	Value chain elements (RI behaviour by other significant actors)			
8.x	Regulatory elements			

7.3 The elements of RI (RIF, Table 2, column 2) – identifying and assessing positive and potential negative outcomes of the innovation

Deciding on what “Elements of RI” to include in the RIF and identifying potential positive and potential negative outcomes of the innovation are two of the most important aspects of this PAS and are an integral part of many other approaches to RI.

Column 1 of the RIF is used to assign a unique identifier to each element identified in Column 2 which that element then retains through to the end of the process. For each main heading listed in Column 2 (1 – 8), there may be several relevant elements, each of which should be numbered in sequence in Column 1 (1.1, 1.2, 2.1, 2.2, etc.), expanding the number of rows to accommodate all relevant elements.

The elements to be included in Column 2 should include properties of the innovation that are of interest to the company and to stakeholders. For the first, baseline version of the RIF, the company can use a range of sources of information to help to decide what elements should be included in the societal, environmental and health-related categories, for example:

- a) researchers working on relevant innovations;
- b) publicly available information;
- c) staff contacts;
- d) contacts with expected customers, perhaps through a process of co-creation of an innovative development; and
- e) the outcomes of any previous stakeholder engagement or survey conducted by the company itself or by others.

Tapping into a broad range of sources external to the company can ensure better quality assessment. If there are no expected elements in one or more of these categories that row can be left blank, recording why this is so.

Most companies may be familiar with the processes of foresighting, for example to anticipate future business and market trends, and many guidance packages have

been developed to enable companies to do this. The process is similar for this PAS but the gaze should be shifted in what might be new responsibility-related directions for some companies. If the use of formal foresighting methods is not feasible for a company, an internal company brainstorming workshop, including a range of staff knowledgeable about the innovation could generate a valid list of relevant elements for the innovation at this stage.

Once an innovation area is being discussed in public, the sources of information noted in this clause may give sufficient coverage of the questions and expectations that the innovation is raising among stakeholders. Where a potentially transformative innovation has not yet been discussed in the public realm, the company may face a more difficult challenge in anticipating positive and negative impacts but here again holding an internal company workshop or brainstorming initiative is a good place to start.

NOTE See Annex A which provides suggestions of the kinds of questions that could be asked in this context.

Another source of useful information on types of public benefit from an innovation that will have societal buy-in, or conversely negative or hazardous aspects that are likely to raise concerns, can be found in the SDGs (Figure 1). The goals listed below are most relevant to specific innovations (with links to further details on each goal). The number in each case is that of the specific SDG in Figure 1.

- a) end poverty in all its forms everywhere⁷⁾ (1);
- b) end hunger, achieve food security and improved nutrition and promote sustainable agriculture⁸⁾ (2);
- c) ensure healthy lives and promote well-being for all at all times⁹⁾ (3);
- d) ensure availability and sustainable management of water and sanitation for all¹⁰⁾ (6);
- e) ensure access to affordable, reliable, sustainable and modern energy for all¹¹⁾ (7);
- f) build resilient infrastructure, promote sustainable industrialization, and foster innovation¹²⁾ (9);
- g) make cities inclusive, safe, resilient and sustainable¹³⁾ (11);

⁷⁾ <https://sustainabledevelopment.un.org/sdg1>

⁸⁾ www.un.org/sustainabledevelopment/hunger/

⁹⁾ www.un.org/sustainabledevelopment/health/

¹⁰⁾ www.un.org/sustainabledevelopment/water-and-sanitation/

¹¹⁾ www.un.org/sustainabledevelopment/energy/

¹²⁾ www.un.org/sustainabledevelopment/infrastructure-industrialization/

¹³⁾ www.un.org/sustainabledevelopment/cities/

- h) ensure sustainable consumption and production patterns¹⁴⁾ (12);
- i) take urgent action to combat climate change and its impacts¹⁵⁾ (12);
- j) conserve and sustainably use the oceans, seas and marine resources¹⁶⁾ (14); and
- k) sustainably manage forests, combat desertification, halt and reverse land degradation, halt biodiversity loss¹⁷⁾ (15).

Many innovations aim to contribute positively to at least one of these goals, and ideally to be neutral for others. Where there is a negative expected impact the company should put in place preventative control or mitigation measures (see 8.4). The web link for each goal leads to a detailed explanation of the issue and how it can be addressed.

Depending on the nature of the innovation, additional issues that could be considered as part of the RIF Assessment include:

- 1) user empowerment;
- 2) mental health and well-being;
- 3) child safety;
- 4) vulnerable or disproportionately affected groups;
- 5) the risks of over-eating and poor diet;
- 6) increasing isolation or loneliness;
- 7) encouraging addictive behaviours; or
- 8) impact on feelings of self-worth or body image.

Column 2, of the RIF (Table 2) should be completed as follows.

- i) Each positive and negative element identified from the above sources should occupy a separate row in the Framework and the column should include all such elements that are seen to be relevant, along with an explanation of the reasons for its choice.
- ii) Each element should have a unique identifying number in Column 1 of the RIF.
- iii) Where the same innovation is being developed for several markets, perhaps at different speeds, depending on the extent of the difference and impact potential, either a separate row should be included for each expected market or a separate RIF should be developed for each.

- iv) All identified **societal, environmental and health-related elements** should be included in a way that is specific enough to enable follow-up scrutiny of changes in impacts as the innovation progresses towards market availability and beyond.
- v) The **value chain elements** refer to a company's need to assure itself that business partners involved throughout an overall value chain are complying with equivalent responsibility standards. This row can be used to record any actions taken to monitor and ensure the responsible behaviour of such companies, probably a different set of companies for each innovation being developed.
- vi) **Regulatory elements** cover compliance with existing relevant legally-based regulations, guidelines and standards. Where the regulatory environment is evolving along with the innovation, regular monitoring and follow-up will be required across all stages of development to keep up to date. In addition, for a novel, transformative innovation, the future regulatory system may initially be uncertain or non-existent and collaboration is required between regulators and innovators to devise the future regulatory system. This RIF could provide evidence relevant to such decisions for regulatory bodies.
- vii) All rows in the RIF should be open to the elimination of some elements and the addition of others as the innovation progresses towards market launch and beyond.
- viii) Where an element is no longer relevant as an innovation progresses through later stages of development, it should be retained in the list as evidence that it had been considered in the past, the change in status being recorded in Column 3.

Company management procedures should encourage cross-referencing between the RI process and updating of the corporate risk register. For example, where the above process identifies reputational risks that are not represented in the corporate risk register, it should be updated to include them.

¹⁴⁾ www.un.org/sustainabledevelopment/sustainable-consumption-production/

¹⁵⁾ www.un.org/sustainabledevelopment/climate-change/

¹⁶⁾ www.un.org/sustainabledevelopment/oceans/

¹⁷⁾ www.un.org/sustainabledevelopment/biodiversity/

For this baseline version of the RIF, Column 3 should be used to record the information that was available to the company at the time of the baseline assessment, and that led to the inclusion of an element in Column 2.

7.4 Identifying relevant stakeholders (RIF, column 4) – who to engage with

Engaging with stakeholders is a requirement of all RI frameworks and is included as an element of organization-level standards such as BS ISO 26000 (Clause 6). At the level of individual innovations, companies should consider relationships with third party actors – how the innovation might affect them and how they might want to influence the development of the innovation. Perceived societal needs are often the incentive for a company to undertake an innovation. On the other hand, when value chains are disrupted, and new players enter the market or existing players radically alter what they do, there is an increased risk of unintended consequences, potentially leading to reputational damage and business risk along the supply chain. It is possible, with careful planning to mitigate these risks, but resilient solutions require careful thought and implementation.

The definition of a stakeholder (see 3.7) includes anybody who cares about a topic, and some of those who regard themselves as stakeholders may not have been identified in the early stages of development of an innovation or may only develop an interest at the later development stages and so the company should be open to expanding the stakeholder list on request.

For this baseline version of the RIF, the company should attempt to identify as many of the relevant stakeholders as possible. Some stakeholders are particularly relevant to specific elements of RI identified in Column 2 of the RIF and such links should be identified in the list in Column 4. This stakeholder list can evolve throughout all later stages in the development process and into the marketing follow-up period. Failure to engage with relevant stakeholders, even if they are only identified in the later translational stages of innovation development, can cause reputational damage for a company.

Having the involvement of a broad range of committed stakeholders, including in the following categories, is an important asset for a company when it comes to balancing the expectations of different stakeholders. A starting point is to identify the kinds of perspectives that could usefully be included, such as:

- a) co-developers of the innovation:
 - 1) other companies and organizations involved as business partners in the product value chain (research organizations, technology suppliers, retailers, R&D partners); and
 - 2) industry interest-groups acting on behalf of specific industry sectors;
- b) markets, customers, end-users;
- c) regulators and standards bodies;
- d) NGOs representing specific groups of civil society stakeholders: e.g. environmental advocacy groups, patient groups; and
- e) individual citizens likely to be affected by an innovation.

Stakeholders can input into the thinking and design of better products or services in ways not previously envisaged by the company. An example would be the role of patient groups in collaborating with companies in the development of novel medical treatments.

Including and balancing the perspectives of a broad range of stakeholders, and making sure that each is aware of the perspectives of all the others involved, is an effective way of moderating the expectations for influence of any one stakeholder group and contributing, where possible, to a balanced consensus that should cover ethnic, geographic and other group identities.

The following sources can provide information on who should be regarded as a stakeholder, what benefits they expect from an innovation and what issues they are likely to be concerned about.

- 1) For important innovations, societal engagement may already have been conducted by academic researchers or through independently commissioned surveys during the early research phases of development. They can often be in the public domain and are a useful source of information about stakeholders and their expectations.

- 2) Engagement with regulatory and standards bodies relevant to the innovation being developed can alert the company to any potential health or environmental hazards and the stakeholders for whom they would be relevant.
- 3) Through engagement with customers and markets for the innovation the company will have an understanding of the benefits to be offered to customers/users, the attractiveness of these benefits and any anticipated disadvantages.
- 4) Social media can be monitored and insights sought from attendance at conferences or public events, to generate awareness of societal expectations for, and concerns about, the innovation(s).
- 5) Other societal actors like writers and film-makers or political actors like advocacy groups may already have begun the process of framing an innovation for the public and this should be taken into account in subsequent engagement.

From such sources the company should develop a list of stakeholders relevant to the innovation(s) being developed and the issues of concern to them, linking these stakeholder concerns to the relevant specific elements identified for Column 2 of the RIF.

NOTE *Attention is drawn to the requirements of the EU General Data Protection Regulation (2016) [9] in developing and updating stakeholder lists.*

7.5 Taking Action

For the baseline RIF assessment, Column 5 includes actions related to a company's need to gather more information on elements identified in Column 2 and also to identify and make contact with specific stakeholders or groups.

8 Innovation-specific responsibility – iteration and updating

8.1 General

This Clause describes what is needed for a company to use the RIF in an iterative way throughout the development of an innovation and to continue to monitor its RI performance in the market place. This description is intended to apply to all innovative industry and commercial sectors, while recognizing that different types and levels of use of the RIF are appropriate for different sectors.

The timescale for updating the RIF should be appropriate to the speed of development of the innovation, and often enough to be able to influence its development if necessary. This could be timed to coincide with updating of the company's risk register or with any other staged procedure the company uses for monitoring the progress of the innovation. The sequential versions of the RIF will provide a record and evidence of the company's activities in ensuring responsible innovation and, as it evolves alongside the innovation, some elements may become redundant and new elements may need to be added.

The series of RIFs developed by a company for each transformative innovation, or group of innovations, thus combines foresighting of future trajectories and impacts (positive and negative) arising from an innovation, repeated at appropriate intervals, along with records of initiatives undertaken as a result of that foresighting to demonstrate responsibility in overall development of the innovation.

Columns 3 to 5 in the RIF allow a company to demonstrate how it has taken account of its responsibilities by recording the outcomes of the following processes:

- a) identifying and noting changes to elements during the development of the innovation (see 8.2);
- b) updating the stakeholder list and engaging with stakeholders (see 8.3); and
- c) taking action (see 8.4).

These components guide the company in managing RI internally and in interacting with stakeholders. They also provide a template for reporting internally and externally on actions taken and the reasoning behind such actions, and to support ongoing management review.

8.2 Identify and note changes in elements since the previous iteration of the RIF (RIF, Column 3)

For the first version of the RIF (Clause 7) the focus was on deciding what elements to include in Column 2 and why (Column 3), allocating a unique identifying number to each. Beyond this point, the company should reflect on each element and the issues it raises, particularly any changes since the previous iteration, for example, positive or negative implications of changes in the development plans for the innovation. A decision should also be taken on whether any elements need to be added or could be deleted.

This process will then guide further stakeholder engagement initiatives (see 8.3) and any subsequent actions by the company (see 8.4). As described in 7.3, this can involve future-oriented anticipation of outcomes that could support or challenge a company's ability to innovate responsibly based on stakeholder engagement and other information sources.

Column 3 is used to record, for each relevant element:

- a) reasons for any changes to the element in Column 2 (e.g. additions or deletions relating to process or to the evidence base);
- b) actions of other relevant parties; or
- c) changes in the salience of an element for the company or for specific stakeholders throughout the development of the innovation.

It is important to ensure that all elements in Column 2 (relevant to stakeholder perspectives, changes in regulatory systems and standards, and the RI-related behaviour of value chain actors) are monitored for change and given the appropriate level of attention.

8.3 Identify and engage with stakeholders (RIF, column 4)

Having identified relevant stakeholders for the baseline version of the RIF, subsequent iterations should:

- a) note any changes in the stakeholder environment and in potential implications of the elements of the innovation identified as being salient for stakeholders;
- b) identify any stakeholders to be added to, or removed from, the list; and

- c) as far as possible, engage with stakeholders to learn about their expectations and potential concerns about the innovation, noting reasons for selecting who to engage with, and the issues raised.

The guidelines in Table 3 encourage productive engagement with stakeholders and help to avoid unrealistic expectations by all parties. For an innovation with societal, health and/or environmental implications, there may not be consensus on the best outcomes for the company or for society. Companies have an important role to play in facilitating the harmonious development of innovations but they can also unwittingly stimulate societal opposition to an innovation, and it is possible for the ill-conceived actions of one company to tarnish the reputation of an entire sector.

Many companies are unfamiliar with the process of stakeholder engagement and there are some potential pitfalls. It is important to find ways to engage with stakeholders that fit with the company's resources and the nature of the innovations. The point is to be able to demonstrate that the company's self-imposed responsibilities are relevant to the issues raised by the intended innovations and that they have taken appropriate actions.

The following list summarizes some of the challenges faced by companies undertaking stakeholder engagement for an innovation and reinforces the case for demonstrating clearly to stakeholders that innovation is being undertaken responsibly.

- 1) The diversity of innovations under development and the rapid pace of some developments may challenge a company's capacity to devote the time needed to consider how specific innovations can be developed responsibly, often in the face of conflicting societal demands.
- 2) The increasing pace of new discoveries and the intensity of international and national competition can make it difficult to find stable ground on which to conduct discussions with stakeholders or to reach a closure that may permit a company to move forward with development of an innovation.
- 3) Where there is low public awareness of an innovation, there is a need to frame it in the minds of stakeholders before they can begin to discuss it constructively. Good design of the engagement process is therefore particularly important.

- 4) Some innovations may require the setting up of new business models and value chains, involving more than one company, to deliver the new development to its intended market, requiring a coordinated cross-company approach to delivery of responsibility.
- 5) There may not be consensus among stakeholders about the relative benefits and risks of an innovation, and stakeholder perspectives can be influenced by widely differing interests and values. In some cases stakeholder engagement may cut across deeply held societal values for some constituencies, potentially leading to discussions that are characterized by entrenched positions and lack of consensus. The guidelines in Table 3 are designed to help avoid such situations and the involvement of independent auditors and/or trusted third parties can also be useful here.
- 6) There are diverse and often rapidly evolving societal expectations for the behaviour of companies developing innovations across different industry sectors (compare for example medical technologies, social media, autonomous vehicles, novel foods).

This Clause suggests how these difficulties can be overcome in a way that is manageable for innovative companies. Most of these challenges are relevant to engagement with groups of stakeholders, which can be a very important part of responsible innovation. However, this should not be at the expense of the equally important process of one-to-one engagement which, for some stakeholders, may be more acceptable than participating in a group activity. Such one-to-one initiatives should also be recorded in the RIF.

8.3.1 When to engage

Engagement has to take place before the innovation has reached a point where adaptation based on stakeholder engagement is not feasible. Making RIF-driven changes early can be beneficial to the company in:

- a) avoiding future additional cost of redesigning a product/service to meet stakeholder expectations;
- b) reassuring potential investors that the proposed innovation is being well managed;
- c) delivering products that are more effective and safer for customers and users; and
- d) reducing the risk of reputational damage.

An additional incentive to engage with stakeholders before the innovation becomes rigidly specified is that, given the opportunity, stakeholders can identify new, unexpected uses of the innovation, particularly if its application is wide-ranging, in different industry sectors.

Engagement should continue throughout the innovation process at intervals that are appropriate to its speed of development (faster development, more frequent engagement), and it can be useful to discuss this timetable with stakeholders. Frequency of iteration and number of iterations overall can also depend on the nature and extent of changes made to the innovation during its development, any other circumstances that would elicit a need for re-iteration, and the degree of stakeholder interest and involvement.

Monitoring and engagement should also continue beyond market launch, gathering information on whether the innovation is performing as expected, whether any new uses or applications are emerging, or whether any new sets of stakeholders or issues have become relevant.

8.3.2 How to engage with stakeholder groups

The capacity of a small company to engage with stakeholders can be limited, perhaps to the organization of one or two focus groups with a representative range of stakeholders, potentially with the assistance of carefully chosen third parties. On the other hand, a large company may already have a standing panel of stakeholders previously identified as being relevant to their business, and the company should then consider whether any additional stakeholders should be added to the panel.

It is important for companies to engage directly with stakeholders, either on a one-to-one basis or as groups. The extent of engagement should be proportionate to the scale and importance of the innovation and a major transformative innovation may justify having a dedicated stakeholder panel that meets regularly during its development.

Most stakeholder engagement initiatives that are feasible for a company to undertake are likely to be small scale and organized locally. They may be carried out by company staff if the skills are available in house, or guided by or commissioned from an external organization, preferably a professional consultancy that does not have any vested interests or perceived conflicts of interest in the outcome. They can involve, for example, focus groups including all stakeholders identified as relevant for a particular stage of development of an innovation, recognizing and recording the interests and values relevant to each stakeholder.

Similarly, if an innovation and the issues it raises justify undertaking a broad-based, formal, statistically verified stakeholder survey, this should be done by an impartial body (e.g. a reputable market research organization) that does not have any vested interest in the outcome. Given the cost of such an initiative, it would probably need to be commissioned by an organization representing an entire industry sector or by a public body, rather than by a single company. This route has the advantage of separating the issues of general interest to the innovation area from the products and services that are specific to any one particular company.

Questionnaires distributed via social media are also an attractive approach for companies, but the people responding will not be identifiable and this approach can be subject to “write-in” campaigns by groups with particular agendas related to the innovation. This approach cannot be expected to give results that are representative of the general population, but it can still give a company a useful basis for judging how to undertake innovation responsibly and how to respond to the expectations of different stakeholder groups.

Companies undertaking stakeholder engagement themselves, or commissioning it from other organizations, should make sure that there is an equitable balance both in the extent of influence on their decision making by different stakeholder interests and values and in their coverage of the full range of issues relevant to the innovation. The same points should be kept in mind in assessing evidence about stakeholder perspectives that comes from engagement initiatives undertaken by others external to the company.

The guidelines in Table 3 [10] can help in the management of engagement initiatives, with a view to enabling consensus as far as possible, and achieving balance across diverse stakeholder perspectives. The underlying assumption is that it is not enough for companies themselves to behave responsibly; all stakeholders involved in an engagement have a duty to behave responsibly, as advised in these guidelines. These guidelines are therefore part of the process of achieving balance (see 3.1) in all the senses relevant to this PAS:

- a) across different sets of ethical principles, e.g. between innovation and precaution;
- b) between different power structures occupied by different stakeholders;
- c) between benefits and risks of innovations; and
- d) across the varied interests and values relevant to different stakeholder groups.

Table 3 – Responsible engagement guidelines

a) Ensure equitable treatment across all stakeholders: <ul style="list-style-type: none"> i) discussions should be open and accommodate the full range of relevant opinions; ii) agendas should be flexible and allow stakeholder input; and iii) no single perspective should dominate other opinions or dictate the terms of engagement.
b) As part of a staged approach to RI, specific aspects of the engagement should be tailored to the relevant development stage to consider: <ul style="list-style-type: none"> i) who should be involved; ii) which topics are relevant to be addressed; and iii) whether and how the outcomes should be implemented.
c) Engagement should be carefully timed: <ul style="list-style-type: none"> i) too early (upstream) and its value will be undermined by uncertainty about the nature of future developments; ii) too late and it may be too expensive to change the design of a particular commercial offering, or stakeholder opinions and political positions may have become entrenched so that accommodation or consensus will be more difficult to achieve.
d) Accept that consensus may not be attainable and manage expectations accordingly.
e) The dialogue should inform stakeholders about the nature of innovation processes – how scientific discoveries are translated to useful products, processes and services and how they will be regulated.
f) Ensure a balanced consideration of benefits and risks associated with the innovation, and where its impacts accrue.
g) Do not allow the values and/or interests of one stakeholder group to restrict the freedom of choice of others.
h) Include standards for the quality and breadth of evidence that is considered as a basis for discussion and decision making.
i) Where there are conflicting values and interests, be equitably sceptical about the impartiality of evidence presented in support of any particular case.
j) Where there is conflicting evidence, consider carefully the expertise of those promoting the evidence, including both scientific and experiential expertise, and weight it accordingly.

These guidelines will help a company to demonstrate responsible behaviour throughout the development of an innovation, including the extent to which it fulfils the aspirations of citizens, as customers for, or users of, the innovation.

8.3.3 What to engage about

The topics for engagement with stakeholders (what to engage about) are the elements listed in Column 2 and the relevant factors noted in Column 3 of the RIF. They should emerge from the company's internal processes (see 8.2) and external engagement with stakeholders as described in this Clause.

8.4 Taking action (RIF, Column 5)

The internal company deliberations and engagement with stakeholders (see 8.2 and 8.3), in most cases, require the company to take some actions relevant to further development of the innovation. Column 5 should record what actions the company has taken, or intends to take, to respond to, mitigate and/or control any issues identified, including those raised by stakeholders. This completed version of the RIF should then be the basis for its next iteration, on a timescale that has already been decided (see 8.1).

Given the diversity of stakeholders and their perspectives it is important to manage expectations about the extent to which the views of any stakeholder or group of stakeholders can dominate the outcome for the company. Demonstrating that the views of stakeholders have been recorded and noting the actions taken (or explaining why one potential action was rejected in favour of another) is necessary. This provides the evidence base against which stakeholders, including citizens in general, can be reassured that innovation is being conducted responsibly at each iteration of the RIF.

Where required actions are identified, the company should put in place appropriate measures or adapt or reconfigure the innovation to deliver the required outcomes. Relevant actions should be specific to the innovation and end-use being developed and the stakeholder perspectives on that innovation. Examples would be:

- a) adjustments to the business model;
- b) changes in the innovation's future development pathway;
- c) targeting additional markets or avoidance of markets where there is anticipated environmental or societal damage;
- d) tighter control of supply chains or contributing to new or different supply chains;
- e) control of access to media or software;
- f) changes to worker contracts or working conditions;
- g) identification of new health-related benefits or changes to conditions of use to avoid health damage.

If sufficiently serious negative impacts are identified, the company should consider not going ahead with the innovation as originally conceived.

Taking RI-related action includes both adopting a balancing process to weight the relative importance or salience of differently-held perspectives (4.4 and Table 3), and making clear the reasoning behind such decisions. However, there is no common scale across which the different elements can be balanced, so it is important to articulate in the RIF the contrasting stakeholder perspectives with a view to achieving at least respectful disagreement.

It is also important to be aware that the location of such a balancing point can change as the innovation moves across the various stages of the development process, or in different end-uses.

The actions documented in Column 5 of the RIF should accumulate throughout the development of the innovation and it should be clear in Column 5 and in the overall report (Clause 9) which actions have been completed and which are still outstanding, continuing if necessary beyond market launch.

9 Overall report

All records of a company's RI procedures should be retained, including sequential versions of Table 1 and Table 2 (the RIF), and any associated notes. For each iteration, there should also be a summary report that explains the issues considered, the processes undertaken, and the outcomes. The report plus the related versions of Tables 1 and 2 (the RIF), along with associated notes, provide the evidence base for the company to draw on to demonstrate its commitment to responsible innovation. There should be a clear trail along the timeline of development of the innovation, through sequential iterations of the RIF, demonstrating the evolution of the company's approach to RI.

Transparency is beneficial for a company and ideally the contents of the RI report and supporting documents should be open to public inspection. However, innovators need to balance their desire for openness with the realities of competitive market places and IP law. Companies should therefore ensure that public engagement or disclosure do not put at risk future filing rights of potentially important intellectual property, including patents, trademarks and registered designs. In such cases, the company should give equivalent attention to all the procedures described in this PAS and retain all records as recommended with a view to making information public as soon as possible. Where full disclosure is difficult, one way of giving public assurance on RI procedures would be to appoint a third party, that is trusted by all those involved, to provide accreditation.

There should be a demonstrable commitment to RI from all divisions and management levels of the company, whatever its size. Where development of an innovation involves collaboration with other companies or organizations, either as sources of expertise or partners in contributing to an overall value chain, the company should attempt to demonstrate that all such organizations have equivalent RI-related commitments (RIF, Element 7). There should also be a parallel commitment to monitoring the regulatory environment, particularly for transformative innovations, and to implementing any changes or other developments that take place between iterations (RIF, Element 8), alongside the relevant societal, health and environmental elements (RIF, Elements 1 to 6).

If any innovation or class of innovations becomes particularly contentious or societally divisive, beyond the capabilities of individual companies to constructively engage with stakeholders, third party involvement, for example of government, trade associations and/or learned societies, might be needed to conduct larger-scale, impartial stakeholder engagement and/or to intervene through policy or regulatory initiatives with the public interest in mind.

Annex A (informative)

Questions to ask about benefits and risks

A.1 Potential benefits of an innovation

What are the goals, purposes and intended applications of your innovation?

Who or what might benefit from your innovation?

Consider all potential groups of beneficiaries: individual users, groups or society and environment as a whole.

Are the benefits common to the application type, or specific to your innovation?

How will you monitor and test whether your innovation meets these goals, purposes and intended applications?

How likely are the benefits and how significant?

How are you assessing what the benefits are?

How are these benefits obtained by your stakeholders?

Can the benefits of your innovation be demonstrated?

Might these benefits change over time?

A.2 Potential risks of an innovation

What might be the risks of other foreseeable uses of your innovation, including accidental or malicious misuse?

Do you have a process to classify and assess potential risks associated with use of your innovation?

Who or what might be at risk from intended and or unintended uses of your innovation, including individual users, groups, society as a whole or the environment?

Are those risks common for an application area or innovation, or specific to your innovation?

How likely are the risks, and how significant?

Do you have a plan to mitigate and manage the risks?

How do you communicate the potential risks or perceived risks to your users, potentially affected parties, purchasers or commissioners?

How do third-parties or employees report potential vulnerabilities, risks or biases, and what processes are in place to handle these issues and reports?

How do you know if you have created or reinforced bias within your system?

As a result of assessing potential risks, are there customers or use cases that you choose not to work with? How are these decisions made and documented?

Bibliography

Standards publications

BS ISO 26000:2010, *Guidance on social responsibility*

ISO/DIS 56000, *Innovation Management – Fundamentals and Vocabulary* [3.2.1]¹⁸

Other publications

[1] EUROPEAN UNION. *Responsible Research and Innovation: Europe's ability to respond to societal challenges*. Luxembourg: EU, 2012. Available from: https://ec.europa.eu/research/swafs/pdf/pub_public_engagement/responsible-research-and-innovation-leaflet_en.pdf

[2] Commission of the European Communities (2000) Communication from the Commission on the Precautionary Principle. COM(2000) 1 final. <https://publications.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en>

[3] European Risk Forum (ERF) (2015) *The Innovation Principle – Overview*. http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf

[4] European Political Strategy Centre, (2016) *Opportunity Now: Europe's Mission to Innovate*. EPSC Strategic Notes, Issue 15, 5 July, 2016. (https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_15.pdf)

[5] Nuffield Council on Bioethics (2011) *Biofuels: ethical issues*. pp 77-79 http://nuffieldbioethics.org/wp-content/uploads/2014/07/Biofuels_ethical_issues_FULL-REPORT_0.pdf

[6] European Political Strategy Centre, (2016) *Towards an Innovation Principle Endorsed by Better Regulation*. EPSC Strategic Notes, Issue 14, 30 June 2016. https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf

[7] Tait, J., Banda, G. and Watkins, A. (2017) *Proportionate and Adaptive Governance of Innovative Technologies: a framework to guide policy and regulatory decision making*. Innogen Institute Report to the British Standards Institution. <https://www.innogen.ac.uk/reports/1222>

[8] UNITED NATIONS. *Sustainable Development Goals*. Available from: <https://www.un.org/sustainabledevelopment/sustainable-development-goals/>

[9] <https://gdpr.eu>

[10] Lyall, C. and Tait, J. (2019) Beyond the Limits to Governance: new rules of engagement for the tentative governance of the life sciences. *Research Policy*, 48(5), 1128-1137. doi.org/10.1016/j.respol.2019.01.009

¹⁸⁾ In preparation

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