Abstract. Most developed countries have in place a full programme of legislation to address a variety of radiation safety issues including protection of individuals, protection of the environment, protection during modal transport of materials and protection of those involved in human volunteer/clinical trials involving the administration of ionising radiations. The UK is no exception to this. Within the UK pharmaceutical sector, companies have had in place robust and well established radiation protection programmes that sought to fully fulfil these legal requirements. As with most ‘company based’ programmes, these had similar top level objectives such as corporate ‘identity’, safety culture, style and philosophy, management structure and local organisation/resource allocation. The recent unprecedented spate of mergers in this industrial sector have challenged the status quo, and in the case of the Glaxo Wellcome Research and Development Limited (GWRD) and SmithKline Beecham (SB) merger, afforded a choice of strategy. Firstly, either do nothing and attempt to operate existing systems on heritage sites, or secondly to integrate the two parent programmes by ‘benchmarking and cherry picking’ aspects of best practice from both whilst also taking the opportunity to address related organisational business alignment issues and fully accommodate advancing technology such as high throughput screening systems. The second option was chosen and this paper outlines the objectives and methodology of the integration process, highlighting key technical, motivational and organisational challenges and summarising achievements to date. The application of the approach taken is discussed as more general model for combining safety related functions during a merger process.

1. Introduction

The merger between GWRD and SB in December 2000 brought together two well-established and effective radiation protection programmes within the respective R&D (UK) organisations. These had been developed over a period of years to ensure compliance with UK legal requirements: the key statutory instruments involved were the Radioactive Substances Act 1993 [1] (relating to site holdings of radioactive materials and waste disposals), the Ionising Radiations Regulations 1999 [2] 1985 [3] (relating to protection of employees and others affected by work activities involving ionising radiations), the Ionising Radiations (Medical Exposures) Regulations 2000 [4] (relating to human volunteer/clinical trial studies) and various modal transport operations [5, 6, 7, 8, 9].

The heritage SB organisation had a programme based on 19 Local Rules [10] produced for their Occupational Safety and Environmental Affairs Department (OSEA) by the Radiation Safety Officer (RSO) addressing the whole range of radiation protection issues: these Local Rules were signed off by the OSEA Head, and tended to adopt a generic and flexible approach, particularly towards area designation, risk assessment and monitoring, often necessitating only a small amount of local departmental supporting documentation to be produced. A Radiation Protection Supervisor (RPS) infrastructure was in place on all sites, along with a system of site radiation safety committees that met thrice yearly. Dosimetry, monitor calibration, waste management, and some training services were provided by contract. Much responsibility for the day to day administration of the programme was devolved to the RPS’s. The roles of Radiation Safety Officer and Radiation Protection Adviser (RPA) were occupied by members of OSEA.

The heritage GWRD organisation had a radiation protection programme based on 18 top tier Codes of Practice [11], produced by the Radiation Protection Officer (RPO) for the Safety and Environment Department, and again addressing most key radiation protection issues. These documents were signed off at the board level and in essence provided instructions to departments on how they should manage
and document their uses of ionising radiations: this often required the production of considerable local
documentation, usually by local RPS’s in collaboration with the RPO. A full RPS infrastructure was in
place and some radiation protection services such as dosimetry, monitor calibration and training were
provided by contract.

Superficially, the GWRD and SB systems appear similar but there were significant philosophical
differences between the programmes:

(a) GWRD documents tended to be more top tier and prescriptive, rather than directly functional at
departmental level;
(b) GWRD documents did not offer generic risk assessment templates – this was a local
responsibility;
(c) the two organisations had different criteria for area designation, contamination monitoring and
dosimetry, along with different detailed RPS responsibilities;
(d) the two organisations had different radiation work and personnel registration procedures;
(e) the two organisations had different stock control/record keeping procedures (GWRD had an
in-house computer system backed by paper records; SB had a commercial computer system with
very few paper records);
(f) contracted services were provided by different organisations, and the scope of such services
varied (SB had contracted out certain laboratory contamination monitoring duties, GWRD had
not).

The merger therefore offered a good opportunity to cherrypick the best aspects of both heritage
programmes and develop new systems that would clearly align themselves with the innovative
multi-site research structure of the new organisation and permit a safe yet flexible approach to work
with ionising radiations. Additionally, opportunities for synergy savings via use of single contractor
organisations for the provision of certain services was apparent. These reasons, coupled with the need
to create and develop a new corporate identity (thus moving away from the inevitable factional
disquiet and conflict that accompanies organisational change) made the development of a new GSK
Radiation Safety Programme the obvious way forward: doing nothing and retaining heritage site
systems was just not an option given the flexibility and consistency of approach required in the new
organisation.

2. Methods

Immediately post merger, the RPO, RSO and RPA’s from the heritage organisations formed an
integration team whose objective was to review heritage procedures and from them derive a GSK
Radiation Safety Programme to align with the business structure of the new organisation. The process
is presented in Scheme 1. Flexibility, pragmatism, user friendliness and synergy savings were
watchwords, although as expected legal compliance remained top priority. Some 15 priority areas were
chosen as the backbone of the new programmes: these are listed in Table 1. The integration team
performed a compare and contrast study on the heritage systems using the priority areas as a focus.

A first pass using this technique readily identified the best way forward for GSK on many of the key
issues. In some cases it was immediately apparent that one heritage system would (with relatively
minor amendments) clearly align itself with the new business requirements (e.g. the heritage SB
arrangements for user/work registrations and the heritage GWRD arrangements for x-ray generating
equipment). In other cases a combination of key facets taken from both heritage systems was felt to
offer the best solution (e.g. training, where the heritage GWRD Introductory Radiation Training
scheme was retained along with the heritage SB RPS Refresher Training scheme and the outsourced
RPS training used by both heritage organisations.).

Further cases were not so easy to deal with by this methodology as they tended to reflect that cultural
differences between the heritage organisations. Extended discussion of these cases resulted in
compromise: risk assessment, for example, eventually adopted a generic stance as found in the
heritage SB systems but adopted a rigorous set of threshold triggers to initiate individual experimental
assessments, more akin to former GWRD practice. Area designation and monitoring topics were also resolved this way after much discussion, mainly centred around threshold action limits for both designation and decontamination actions.

The advent of new technologies such as high throughput screening arrays for molecular biology assay has also presented challenges in radiological protection. Such systems often operate semi-automatically and remotely, and whilst individual assays may use very low amounts of radioactive material, paradoxically there may be enhanced radiochemical usage (brought about by the increased throughput volume). The integration process sought to rationalise control of radioactive materials used in such systems and also related waste packaging/disposal methodologies.

The presentation of these new systems as the Radiation Safety Programme to the company followed a consultation process whereby comments were invited from key internal stakeholders. Structured RPS briefing sessions were the key route for their launch, backed up by individual meetings with customer groups. The engagement of the RPS’s and other stakeholders prior to the launch of the new Radiation Safety Programme by opinion surveys [12] and by the consultation process itself minimised cognitive resistance to the changes: this was also aided by RPO/RPA transparency in explaining the methods adopted to derive the programme from heritage systems.

Additionally the existence of certain cross-company fora, in particular the Pharmaceutical Industry Radiation Safety Discussion Group (PIRSDG) founded in the early/mid 1990’s to promote the exchange of best practice in radiological protection within the sector, aided the merger process in several ways: firstly, the heritage RPO/RSO and RPA’s were active in this forum and thus knew each other professionally prior to the merger and, secondly, surveys carried out under the auspices of PIRSDG had contributed to a general understanding of how various pharmaceutical companies organised and managed radiation safety in the UK. This clearly assisted with both the inter- and intra-company benchmarking exercises, leading to the establishment of a world class Radiation Safety Programme for GSK R&D (UK) Ltd.

3. Results

After the consultation process, the GSK R&D (UK) Ltd Radiation Protection programme went live on 1 April 2003 and has been well received by both management and users. The key topics listed in Table 1 formed the basis of this and the new systems have demonstrated themselves as flexible and robust and have stood the tests of inspection and auditing by both GSK Corporate Environment, Health and Safety and UK national regulatory authorities. User acceptance and compliance appears good and continues to be monitored. Synergy savings of several thousand pounds have been gained by seeking common contract providers for some training modules, dosimetry provision and monitor calibration. A common commercially available computer package is now used across all relevant sites to monitor the acquisition, use and disposal of radioactive materials and has become the prime record keeping tool, thus eliminating many departmental bases paper systems. New technologies, such as the development of high throughput screening arrays for molecular biology assays have also been successfully integrated into the new Radiation Safety Programme on a cross site basis.

4. Conclusions

The process for merging the two robust and well established radiation protection systems for GWRD and SB into a new Radiation Safety Programme for GSK R&D (UK) Ltd has worked effectively. This owes a lot to the spirit of transparency, clear objectives, mutual trust and performance with integrity principles adopted by the integration team. Timely and effective consultation with stakeholders, coupled with the clear identification of opportunities for synergy savings have lead to the launch of a Radiation Safety Programme that is flexible enough to support the new R&D organisation with a minimal bureaucratic burden, but retains sufficient control to ensure legal compliance and to accommodate advancing technologies.
The formation of topic based integration teams, following similar procedures to those described above was in fact the basis for development of the entire GSK R&D (UK) Ltd safety and environment programme. The approach taken is not, however, an easy option, requiring, in the case of the GSRD/SB integration, up to two years intensive input from relevant safety and environment topic specialists and various stakeholders.

The combined GSK R&D (UK) organisation now covers eight research sites; a total of ca 800 employees are registered users of ionising radiation and ca 100 RPS’s and deputies are appointed. A full range of work with ionising radiations is undertaken ranging from the synthesis of radiolabelled drugs, metabolism studies, molecular biology applications and assay development to x-ray crystallography, veterinary x-ray facilities and gamma irradiation of cell products. All of these areas now work to the Radiation Safety Programme established by the methodology described above. GSK R&D (UK) Ltd now has two in-house RPA’s who also undertake RPO duties across the eight sites; both are members of the new Environment, Health & Safety Department, devoting in excess of 80% of their time to radiation safety issues.
Scheme 1. The GWRD/SB Radiation Safety Integration Process

Heritage SB systems

Radiation Safety integration team

Heritage GWRD systems

Heritage SB RPS satisfaction survey

Heritage GWRD RPS satisfaction survey

GSK Environment, Health & Safety Department consultation

Draft GSK Radiation Safety Programme

Extended stakeholder and RPS consultation

Final GSK Radiation Safety Programme

Programme launch
Table 1. The 15 Key Topic Areas established by the GWRD/SB Radiation Integration Team as the basis for the GSK Radiation Safety Programme. Some Key Outcomes are Highlighted

<table>
<thead>
<tr>
<th>Topic Area</th>
<th>Purpose</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR01: The Ionising Radiation Safety Programme</td>
<td>To describe the framework and systems that GSK should put in place to ensure compliance with relevant legislation.</td>
<td>A new overarching document detailing management responsibilities, RPS, RPO, RPS responsibilities, and the GSK radiation protection infrastructure.</td>
</tr>
<tr>
<td>IR02: Introduction to Radiation Protection Legislation</td>
<td>To provide a one-stop overview of relevant UK radiation protection legislation and an e-link to relevant certificates issued under RSA93.</td>
<td>The e-link to current certificates was a new development.</td>
</tr>
<tr>
<td>IR03: Documentation, Organisation and Registration</td>
<td>To ensure that appropriate radiation protection documentation is produced and reviewed. To provide template forms for the nomination of radiation users and RPS’s, to provide template forms for the registration of radioactive work. To describe the duties of RPA, RPO and RPS’s.</td>
<td>Defines more clearly roles/ duties of users, RPA, RPO and RPS and established site Radiation Safety Committees and RPA meetings. Registration forms evolved from heritage formats with simplification where practicable.</td>
</tr>
<tr>
<td>IR04: Risk Assessments</td>
<td>To ensure that prior risk assessments are undertaken for all work involving ionising radiation.</td>
<td>Focussed and generic format for common procedures but retained need for specific assessments for high-risk activities. (Relevant guidance provided). Also developed generic emergency responses/contingency plans.</td>
</tr>
<tr>
<td>IR05: Area Designation</td>
<td>To ensure that a methodology is in place to permit appropriate designation of areas where there is potential for exposure to ionising radiation.</td>
<td>Introduced a system of Registered, Supervised and Controlled Areas derived from Annual Limit of Intake (ALI) thresholds derived from generic risk assessments.</td>
</tr>
<tr>
<td>IR06: Use of Unsealed (Open) Radioactive Sources</td>
<td>To ensure that use of such materials complies with relevant legislation.</td>
<td>Set new guidelines for use of protective equipment and organisation of work area.</td>
</tr>
<tr>
<td>IR07: Control of Unsealed (Open) Radioactive Sources</td>
<td>To ensure that such materials are controlled in compliance with relevant legislation.</td>
<td>New electronic ordering and stock control system introduced along with enhanced procedural requirements for receipt of radioactive packages. Waste minimisation emphasised. RPS responsibilities for these processes extended and clarified.</td>
</tr>
<tr>
<td>IR08: Control of Sealed (Closed) Sources</td>
<td>To ensure that the acquisition, use and disposal of such sources complied with relevant legislation.</td>
<td>New record keeping requirements introduced and practical advice on leak testing given for RPS’s.</td>
</tr>
<tr>
<td><strong>Topic Area</strong></td>
<td><strong>Purpose</strong></td>
<td><strong>Outcomes</strong></td>
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<tr>
<td>IR09: X-ray Generating Equipment</td>
<td>To ensure systems are in place to permit the safe operation of x-ray equipment.</td>
<td>Differentiated between open and closed beam systems. Emphasised role of Critical Examinations and introduced arrangements for independent annual inspections.</td>
</tr>
<tr>
<td>IR10: Monitoring</td>
<td>To ensure that appropriate contamination and doserate monitoring regimes are in place</td>
<td>Provided enhanced advise on monitor selection. New thresholds action levels for fixed and non-fixed contamination specified. New monitor calibration system introduced. Routine area monitoring by contract labour available as a resource for RPS’s.</td>
</tr>
<tr>
<td>IR11: Personal Dosimetry</td>
<td>To ensure that an appropriate personal dosimetry service is provided for staff working with ionising radiations.</td>
<td>One provider of dosimetry services selected. New criteria for personal dosimetry and investigation levels specified.</td>
</tr>
<tr>
<td>IR12: Training</td>
<td>To ensure that appropriate training programme is available for those using or who may be affected by use of ionising radiations.</td>
<td>One provider of Introductory training package selected. Common courses for RPS training established. New User training formalised and enhanced. Non-user/third party training programmes developed.</td>
</tr>
<tr>
<td>IR13: Female Workers</td>
<td>To ensure that female workers using ionising radiations are given appropriate risk information in compliance with legal requirements.</td>
<td>Common work restriction criteria established. All female staff given letter outlining radiation risks prior to starting work with ionising radiations.</td>
</tr>
<tr>
<td>IR14: Transport</td>
<td>To ensure that radioactive materials are transported/packaged and labelled in compliance with legal requirements.</td>
<td>Common packaging specifications and transport documentation introduced. RPS responsibilities for package sign-off extended.</td>
</tr>
<tr>
<td>IR15: Clinical Applications</td>
<td>To ensure that human volunteer studies involving the administration of ionising radiation are performed in compliance with legal requirements.</td>
<td>New procedure, incorporating requirements of Ionising Radiations (Medical Exposure) Regulations 2002. Guidance provided to Clinical Departments. Dose constraint criteria for volunteer selection established.</td>
</tr>
</tbody>
</table>
References

12. GWRD and SB RPS satisfaction surveys, 2000, organised by D J Morecombe and A S Muir.