Bulletin

Occasional information for members

Institute of Safety in Technology and Research

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General enquiries about the Institute should be addressed to the Honorary Secretary:

istr-secretary@contacts.bham.ac.uk

Enquiries about membership should be addressed to the Membership Secretary:

istr-membershipsecretary@contacts.bham.ac.uk

ISTR EXECUTIVE COMMITTEE

The executive committee has met at the University of Lincoln in December 2005, HPA Chilton in March 2006 and the University of Birmingham in May 2006. The following is a summary of the matters considered.

Future events

Topics considered for future meetings include: Design for disabled persons, Occupational Health, Skin Management, Pre-screening/tests, DDA, Mutagens, Non-ionising radiation. Topic for November 2006 symposium will be “Enabling the disabled in Science and Technology”.

Membership Certificates

Various options for updating the style and wording on membership certificates were considered prior to a new print run.

Members Handbook

The Membership Secretary is currently converting the database of members into a modern format and checking the currency of all entries. Whilst this has delayed updating the Web version it remains the intention to maintain an updated version on the Web as soon as this work has finished.

ISTR Finances

The level of membership fees, ISTR running costs and the minimum level of reserve fund continued to be kept under review. The current levels of expenditure and income indicate a zero budget. Projects will be budgeted separately.

Joint Ventures

An invitation to join with LASA and IPSE for a meeting on specialised containment laboratories was considered and agreed as it posed little risk to ISTR.

Working Party on Training and Accreditation of BSO's

The first meeting established a number of sub-groups to progress its work.

Bio-Safety Sub Group for Ireland

The first meeting of a bio-safety sub-group set up by Irish members will take place on 21 June at DCU.

A WORD FROM THE EDITOR

Welcome to another issue of the *Bulletin*. The *Bulletin* is a service to and for members. In this issue you will find news of members, details of forthcoming *ISTR* activities, reports of recent meetings a summary of Executive Committee business. If you have any item that may be of interest to other members please let me know.

From time to time, as a further service to members, advertising material may be enclosed with the *Bulletin* but this does not necessarily mean that the ISTR endorses the particular products.

The ISTR is not responsible for individual views expressed in the *Bulletin*.

The Bulletin is edited by: Dr FJ Young, Health and Safety Unit, The University of Birmingham EMail f.j.young@bham.ac.uk

MEMBERSHIP NEWS

The Institute has admitted the following into membership

Further details may be found in the updated, on-line version of *ISTR Members' Handbook 2002* in the members' only section of the ISTR website.

Full Members:

Mr AR Butterworth, Mr P Daniell, Ms KE Davis, Dr RA Gargan, Mr D Gask, Ms A Harris, Mr J Luke, Dr K Mack, Mrs WA Marshall, Dr JP Robinson, Ms RJ Stephenson and Dr PM Veitch

Associate Members:

Mrs GS Brain, Ms B Farrell, Mr CP Ford and Mr S Scott.

Enquiries about membership should be addressed to the Membership Secretary: istr-membershipsecretary@contacts.bham.ac.uk

DATES FOR YOUR DIARY

2006 AGM and Symposium

The 2006 AGM and symposium will be hosted by Dublin City University. The AGM will take place on 21 June. The theme of the symposium on the 22 June will be “Risk Management and the Safety Professional.”

2006 Autumn Symposium

This is entitled "Enabling the Disabled in Science and Technology". Topics to include: What does the Legislation require; Designing facilities which disabled persons can safely use; Adapting the existing – what reasonably can be done; How to do a personal assessment, inclusion programmes; Coping with an ageing workforce. Topics for wotkshops: design of a lab for disabled person; adapting a hall of residence for disabled users.

For more information contact the Events Secretary: istr-eventssecretary@contacts.bham.ac.uk

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ISTR Autumn Symposia, November 2005

The ISTR 2005 Autumn Symposia were held at the Windmill Village Hotel, Coventry on 3 and 4 November. 43 delegates attended the Better Waste Management symposium and the next day 30 attended an ISTR Biosafety Sub-Group symposium on Gene Therapy. *Copies of the presentations may be downloaded from the members' section of the ISTR website.*

BETTER WASTE MANAGEMENT

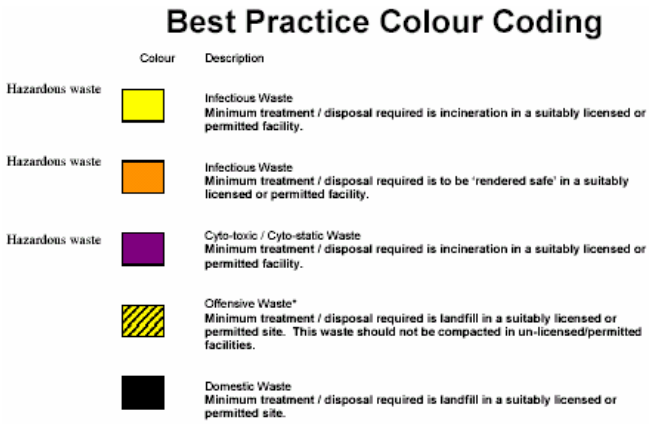
This account of the symposium was kindly provided by David Heath

New legislation & Enforcement
Charles Philips, Environment Agency

Charles Philips described the *Hazardous Waste Regulations 2005.* Of particular note for our establishments is that producers of less than 200 Kg of hazardous waste do not have to register. The number of landfill sites handling hazardous waste has reduced form 255 to 15 and costs have risen 80% For establishments with multiple sites, all must be registered but only one needs to be the ‘waste transfer station’.

Hazardous waste – Healthcare waste
Wendy Raynor, Enviros

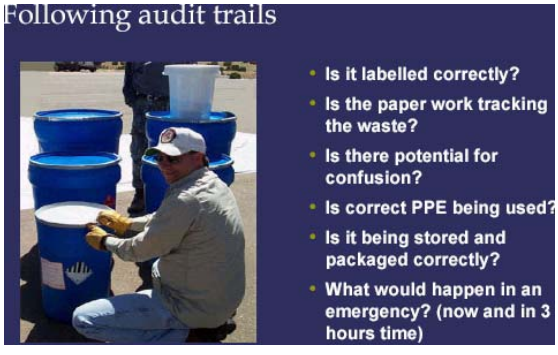
Wendy Raynor talked about healthcare waste and the implications of the introduction of the *Hazardous Waste Regulations* in England and Wales (*The Special Waste Amendment Regulations* in Scotland). The definition of hazardous waste is best found in WM2, on the EA website, based on EWC (European waste catalogue codes). With the introduction of the new regulations there is a need to rewrite the healthcare guidance to improve waste segregation. Using WM2 it is possible to segregate infectious waste depending on its origin and the micro organisms it does or does not contain. Some may be clinical (infectious) some offensive and some domestic. Best practice will adopt a colour coded bag system for infectious (yellow or orange) cytotoxic (purple), offensive (yellow/black) and domestic (black or clear). Segregation should clarify disposal pre-



treatment, appropriate disposal routes and allow costs to be kept down.

Environmental Auditing-are you doing it? Are you doing it right ?
Tom Woollard, ERM

Tom Woollard explained the purpose and process of environmental auditing, to ensure you know where your waste is going and that it is being disposed of in a responsible manner, in compliance with the regulations.



The skill of good auditing is to ask open questions of the waste operator and follow an audit trail, from source in your facility, right to the end, the landfill pr incinerator.

What contractors can do for us
Dave Reynolds, Onyx,

Dave Reynolds gave the waste contractor's role. The contractor can handle your waste but needs the help of the producer, to package the waste in suitable containers and supply information on the nature of the hazards. In addition to routine waste removal, many waste contractors can offer an emergency service 24/7.

Total waste management
Toby Clark

Toby Clark gave an overview of the whole waste management situation with numerous examples of waste horror stories he had encountered.

He explained the duty of care of the producer to manage waste and prevent pollution. He expanded the concept from just waste materials, to include other types of waste, including waste heat and light and how to minimise them as they all have an environmental impact.

WORKSHOPS

The two workshops were repeated to allow delegates to attend both.

Moving labs – disposing of old materials
Steve Owens, HPA

The first workshop looked at the problems of decommissioning an abandoned laboratory. The delegates devised a plan of attack to get rid of the many hazardous materials found hidden away. Both groups decided on an inventory, segregation, prioritisation and then an action plan, involving a contractor for just a few items, most could go down the sink.

Action plans – how we do it

The second workshop called for delegates to set up their own action plans for compliance with the new regulations, based on the presentations heard in the morning.

These involved briefing senior management and safety committees, identifying departments which produce difficult waste, education of staff to minimise waste and competitive tendering from waste contractors.

GENE THERAPY

This account of the Biosafety Sub-goup symposium was kindly provided by John Richmond

Roles and responsibilities – ethics and safety in the clinic (regulatory viewpoint)
Daniel Gooch, Genetic Science Policy Team, Department of Health

Daniel Gooch presented the regulatory viewpoint of the Gene Therapy Advisory committee (GTAC) specifically in relation to patient safety. He emphasised "no approval from GTAC – no trial!" The GTAC comprise 2/3 expert, 1/3 lay members and has 2 main functions:

- To consider ethics
- To advise UK health ministers

GTAC considers that currently all GT is research and not treatment. The Secretariat:

- organizes and runs GTAC;
- organizes public meetings;
- writes documents (including SOPs – downloadable from DoH website);
- talks to international regulatory authorities; acts as firewall for committee; and
- organizes recruitment.

The GTAC annual reports indicate that there have been up to 135 approved GT trials since 1993, with over 70% of the trials for cancer. UK comprise 41% of European and 11% of worldwide activities compared with 66% in the USA. The GTAC reports include:

- reviewed protocols,
- guidance and regulatory issues,

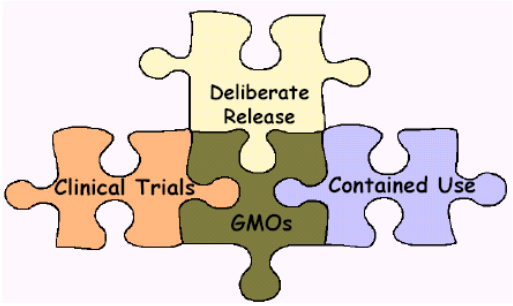
- GTAC public meetings,
- updates of clinical trials and
- GT white paper commitments.

Trials are carried out by Pharmaceutical/ Biotech Companies and NHS researchers whereas GMP vectors are made by Pharmaceutical Companies/ Contract Manufacturers and University/ Academic Labs.

Review of vector-host systems for Gene Therapy with emphasis on new approaches
Dr Paul Logan, Health & Safety Executive, Biological Agents Unit

Paul Logan presented "GMOs in the Clinical Setting". He stated that Gene therapy and GM safety legislation may be covered by either Contained Use or Deliberate Release legislation. Many gene therapy experiments are not GM as defined in the above legislation. However, all those that use GM organisms have been treated under CU in the UK. However, the European position varies between countries.

European Directives covering GMOs in clinical setting



There are European directives governing GMOs in the clinical setting and CU must comply with HSE/ DEFRA/ DH (GTAC)/ Scientific Advisory Committee on Genetically Modified Organisms **(**SACGM) and Medicines and Healthcare products Regulatory Agency (MHRA) legislation. Gene therapy was defined as:- "The deliberate introduction of genetic material into human somatic cells for therapeutic, prophylactic or diagnostic purposes." This includes techniques for delivering synthetic or recombinant nucleic acids into humans.

Paul Logan went on to discuss administrative (including public relations), technical (including agent, patient, waste and monitoring) and environmental issues. Normal hospital waste regimes should be appropriate for handling GT waste.

Biological agent examples from UK 2004 Gene Therapy trials included:

- AdFGF (adenovirus)
- Oncolytic herpes simplex virus
- X-SCID (lentivirus)
- Bladder cancer (adenovirus)
- Cystic fibrosis (lentivirus)

Biological containment and guidance from HSE and DEFRA were also discussed.

In summary, the Clinical environment is very different from a research laboratory and sensible risk management decisions need to be taken to ensure that staff/patients/public and environment are suitably protected. Most future developments are likely to be on vector refinement and scale, together with location and management of GT trials.

Transferring gene technology
Colin Love, Bio Vex

Colin Love talked of the challenges of transforming 'drugs' to medicines.

Currently he is involved in 4 clinical trials and expects to run 6 next year, and he illustrated his talk with a second generation oncolytic cancer therapy – OncoVex GM-CSF – utilizing herpes simplex virus (HSV) - designed to treat metastatic disease.

He discussed aspects of safety and risk assessments relating to the vector, animal models, sterility, purity and viral product before the clinical trial. He highlighted the legislative processes involving the EC Clinical Directive and ICH/FDA/EP guidelines and emphasised the need for good records and documentation.

The Phase 1 clinical trial at 3 UK sites involved 30 patients, with cutaneous/ sub-cutaneous tumours, and intra tumoral injection administration. Patients were treated in low-pressure rooms and confined for approx 48 hours.

The results were promising, with dose related GM-CSF expression, and with most patients showing observable effects, a Phase 2 development is warranted.

Safety issues from vial to patient and how they are managed
Sue Arrand, Clinical Trials Pharmacist at Christie Hospital

Sue Arrand spoke from a personal and practical viewpoint. She discussed receipt of product; use of

SOPs; and storage with controlled access and BMS (and backup in case of failure). Dispensing of Class 1 product required little manipulation, whereas Class 2 was more complex and ideally required a dedicated facility (separate room and adequate space) with a Class 2 BSC; and appropriate staff training. General reassurance from OHD may be required to alleviate perception of risks to staff. Designated sealed biohazard labelled boxes for Class 2 product were used and an audited paper trail was maintained, and disposal was via appropriate licensed, validated route.

At the bed side - from administration to patient discharge and subsequent monitoring of patients
Audrey Griffiths; Senior Nurse Manager and Biological Safety Officer

Audrey Griffiths gave useful practical advice for bedside patient treatment and safety, from the nursing perspective. A number of interesting issues were addressed regarding risk assessment, including patient confinement period.

Workshop exercise

Delegates split into groups for an exercise that comprised a case study based on a real gene therapy application:

"Tasks, requirements and procedures for setting up and conducting a clinical trial with gene therapy agents"

Scenario
A biotechnology company has started running clinical trials of a novel gene therapy and has approached a hospital to seek its consent to carry out a trial there.

A clinician, aware of possible significant benefits to patients is keen to participate in the trial.

What happens now.....?

Group 1 - Initial feasibility considerations

What decisions need to be taken at this particular meeting and what actions should result?

Are facilities available / staff available ?
Will trust policy allow work to go ahead ie PR/ local press etc ?
Is there a BSO / GMSC ?
Is the hospital registered with HSE ?
Background information on points 1-4
Agreement in principle from Chief Exec
Ethics committees – Trust & Uni
Who are sponsors? define and confirm

Will it achieve these objectives given the attendees? Ought others to have been invited, and if so, who?

Invitation to : Chair of GMSC, Pharmacy, BSO, Senior nurse, Clinical director
Feasability study completed ?

How important is it that participants in this management process preserve the independence of their roles? Is cross-over of roles acceptable? How important is it that these people understand the other management processes involved in decision-making?

Independence not essential but patients must have independent counselling
Understand roles in context of overall project

Assuming that the present meeting is convened to establish matters of principle only, should a working group now be established? Who should be invited to contribute their expertise?

Working group to include budget representative

Do formal notifications need to be made to statutory bodies at this stage, if so, what and who should be asked to prepare the notification?

Informal inquiry to HSE – practical aspects on multi site premises.

Group 2 - Establishment of management structures

What decisions need to be taken at this particular meeting and what actions should result?

Define remit of contained use committee to advise on current and future proposals
for gene therapy trials
To appoint a BSO
To appoint a secretary (BSO?)
To review (approve or reject) risk assessments
To invite proposer to the committee to answer any questions concerning his proposal
To decide the frequency of meetings

Will it achieve these objectives given the attendees? Ought others to have been invited, and if so, who?

Objectives cannot be met with existing committee composition so invite :

- University BSO
- an infection control specialist
- a facilities manager
- a nurse
- Trade Union representative(s)

What formal notifications need to be made to statutory bodies and who will do this ?

To ensure compliance with statutory requirements, need to register premises,
GTAC, HSE, MHRA, University, local ethics committee & Trust R&D office

What internal administrative procedures and SOPs need to be followed – and/or set up from scratch?

SOP's need to be written

- GM waste streams
- Pharmacy arrangements
- Administration of GM's (where)
- Theatre arrangements
- Patient info leaflets
- Spill control / emergency procedures

Is this "Contained Use" or "Deliberate Release"? What are the implications?
Contained use

What issues of the communication of information might arise in view of public anxiety about genetic modification technology?
Formal minutes to go to University safety committee
Establish contact (via Ambridge) with other trial centres (view prior trial data)
Publicise work in hospital via
Info sheets
Briefing notes for supervisors
Seminars
Contact patient support group for specific diseases

How impartial is the group listed above?
Balanced committee ? – considered so with additional members

Group 3 - The role of the genetic modification safety committee

The Trust has close links with the School of Medicine of Borchester University. What co-operation should be sought, if any, with the University?
Set up working group to advise the University and trust committees, made up of

- Specialists
- V large unions
- Porters
- Cleaners ethics committee members

Does the Trust really need to set up its own GMSC or could it rely on expertise and advice from the University's GMSC?
What assistance might it consider it needs?
Set up both with cross representation across UNI and trust committees
+ working group from both
Chair person – senior authority
Ethics representative
Safety Adviser (trust)
Medical staff running trial
Virologist (clinical)
Clinical manager
Pharmacist
Academic virologist / molecular biologist
Infection control specialist
Occupational Health rep
Union rep
Staff rep
Chair and BSO from University Committee
Research nurse

How should the GMSC of Borchester University respond to a request for advice from the newly-formed GMSC of the Trust.

Terms of reference for the committees
Working group is advisory

The Trust is trying to resolve practical difficulties with balancing product protection and operator safety issues. It asks the GT Development Unit of the University for permission to use its one of its specialist laboratories to prepare the doses of Saggitarin™ for administration to patients in the trial.

Trust to use Specialist University lab if available
Assume pharmacy has adequate space itself
This needs input from working group to make it work.

No – syringes through public areas
Licensing issues
Secure storage issues

Yes – under the control of the Pharmacist,
Management controls in writing

Current Consultative Documents

The Executive Committee organises formal responses from the ISTR to Consultative Documents (CD's) put out by the Health and Safety Commission, etc. Each such response is intended to be based on the views of the membership co-ordinated by identified individuals. These co-ordinators need to have expertise in a particular area of interest to the *Institute* because the timescales for responses to CD's is sometimes very short and there may be little opportunity for further consultation with the membership.

If you are willing to act in this capacity of "CD" co-ordinator for ISTR please contact Arthur Mitchell, Hon. Sec., and indicate the topic area you have the expertise to cover.

Volunteers are needed NOW for the following.

The documents may be downloaded from the web addresses provided.

Health and Safety Commission

IMPROVING WORKER INVOLVEMENT - IMPROVING HEALTH AND SAFETY

This consultation sets out options aimed at increasing the quality and quantity of worker involvement in health and safety risk management by voluntary initiatives or by strengthening the legal requirements for consultation with employees. The Health and Safety Commission (HSC) and Executive (HSE) state "...we believe that worker involvement is at the very heart of sensible health and safety management. It is a key element of our strategy and we are committed to improve both the quantity and the quality of workers' participation in managing health and safety at work".

In the Consultative Document HSC/HSE:

- describe what they mean by "worker involvement" and why they think it is important;
- look at the three "pillars" of their strategy: legislation; guidance; and encouragement;
- introduce suggestions for how they might strengthen each of these three pillars; and
- ask for feedback about their own suggestions and any new ideas that they might not have considered.

HSC/HSE are organising a number of meetings for people to discuss the Consultative Document. See the web link below for details.

Closing date for comments 8 September 2006
[http://www.hse.gov.uk/consult/condocs/cd207.htm]

Health and Safety Commission

MANAGING WORKPLACE TRANSPORT RISK - A ROUTE MAP

HSE has been devising a cross-cutting guidance tool, called the "Route Map", to help manage the risk involved in the use of workplace transport. Workplace transport is used in a great variety of situations but sadly remains the second biggest cause of fatal injury in the workplace. The control of risk in these circumstances is covered by several sets of regulations and many employers and duty holders find this confusing. Various guidance publications have been developed, some generic, some for specific procedures in certain sectors, but there is no clear cross-cutting guidance on driver skill and management.

The Route Map will provide an easy to understand and readily accessible framework of current legislation, guidance and agreed good practice. It will set out alternative ways to comply where these exist, which should be particularly useful for small and medium enterprises which have many demands on limited time and resources.

Closing date for comments 22 September 2006
[http://www.hse.gov.uk/consult/condocs/routemap.htm]

Department for Environment, Food and Rural Affairs

CONSULTATION ON A PROPOSAL FOR A EUROPEAN COMMISSION DIRECTIVE ON RESTRICTIONS ON THE MARKETING AND USE OF MERCURY IN CERTAIN MEASURING DEVICES

The aim of this proposal is to restrict the marketing of fever thermometers and other measuring devices intended for consumer use (e.g. manometers, barometers, sphygmomanometers) which contain mercury.

The proposal is intended to amend the existing *Marketing and Use Directive* in order to contribute to a high level of protection of the environment and human health by preventing considerable amounts of mercury entering the waste stream. Mercury is highly toxic, persistent in the environment and can accumulate along food chains. Although its use has greatly declined, it still has some applications, including in measuring and control equipment.

It is estimated that 80-90% of all mercury used in measuring and control devices (in the EU) is employed in clinical (fever) thermometers and other thermometers for household use. The quantities of mercury involved remain significant, some 33 tons per year in the EU with around 25-30 tons entering the mercury cycle via thermometers alone. Emissions have reduced as more of this equipment is collected

and the mercury recovered, but they may still be significant. Many domestic products will end up in landfill with the potential for slow, but long term, leaching; they may also be subject to spillages following breakage, with ensuing potential for exposure, especially in the home.

Closing date for comments 21 July 2006.
[http://www.defra.gov.uk/corporate/consult/commdir-mercury/index.htm]

Department for Environment, Food and Rural Affairs

CONSULTATION ON THE REVIEW OF THE AIR QUALITY STRATEGY – OPTIONS FOR FURTHER IMPROVEMENTS IN AIR QUALITY

Despite significant reductions in emissions of many pollutants, air pollution still harms public health and causes environmental problems. Air pollution from man-made particles is currently estimated to reduce the life expectancy of every person in the UK by an average of eight months. In addition, more than half of all natural and semi-natural habitats in Britain still have too high levels of harmful acidity. This is why the UK Government and the devolved administrations are now consulting on a review of the current Air Quality Strategy for England, Scotland, Wales and Northern Ireland.

Views are sought on a number of potential additional national policy measures which, if implemented, could secure further improvement in air quality and move us closer to achieving the Strategy's air quality objectives. Among the package of measures on which the UK Government and the devolved administrations are seeking views are:

- new tighter European vehicle emissions standards (so called Euro-standards);
- incentives for cleaner vehicles;
- further reductions in emissions from small combustion plants; and
- further reductions in emissions from ships.

As well as direct benefits to public health, these new policies have the potential to provide important benefits to quality of life, reducing health inequalities and helping to protect the environment.
The consultation also seeks views on the Strategy's current objectives for air pollutants and in particular:

- a new, more cost effective, policy framework and objectives for controlling pollutants for which there is no safe level such as fine particles (known as PM 2.5);
- improved protection for Sites of Special Scientific Interest and other protected habitats; and
- a new objective on ozone for the protection of our environment.

The consultation document also sets an agenda for longer term action to improve our understanding of air pollutants and attempts to qualitatively assess the potential for further air quality improvements in the very long term.

Closing date for comments 11 July 2006
[http://www.defra.gov.uk/corporate/consult/airqualstrat-review/index.htm]

Department for Environment, Food and Rural Affairs

CONSULTATION ON A PROPOSED VOLUNTARY REPORTING SCHEME FOR ENGINEERED NANOSCALE MATERIALS

A nanometre (nm) is one billionth of a metre. To put this into some perspective, a human hair is about 80 000 nm in diameter. People are interested in the nanoscale because it is at this size that the properties of materials can be very different from those of the same material at a larger scale. Nanotechnologies are defined as the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale. The applications of nanotechnologies are wide-ranging.

The proposed voluntary reporting scheme is part of the programme of work across Government to build the evidence on any potential risks posed by nanotechnologies, in order to move towards evidence-based appropriate controls.

Closing date for comments 23 June 2006
[http://www.defra.gov.uk/corporate/consult/nanotech-vrs/index.htm]

ISTR's ELECTRONIC INTERFACE

HASNET-ISTR Email Discussion List

This is a closed email discussion list. That is, only ISTR members are given access to it. Members need do nothing; members are automatically added to the list by the Membership Secretary using the email address supplied by the member. Queries about HASNET-ISTR should be addressed to the Membership Secretary (see page 2 for contact details).

The Executive Committee would like to see members make a lot more use of HASNET-ISTR

Bulletin

Whilst this copy of the ISTR Bulletin has been posted to you, an electronic version in Adobe Acrobat pdf format and in colour can be downloaded from the member's only section of the ISTR web site: http://www.istr.bham.ac.uk/members/cmem.htm

ISTR on the World Wide Web: http://www.istr.bham.ac.uk/