

Summary of inspections 2006–2008

Public display

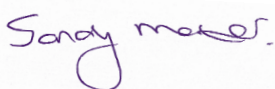
Foreword

This summary inspection report is one of a set of five that the Human Tissue Authority (HTA) has produced for each of the sectors that we license and inspect: anatomy, human application, post-mortem, public display and research. The reports summarise the key learning points from a range of information that we hold about the establishments that we regulate. They are vital reading for anyone who works in these sectors, so that lessons may be learnt and standards improved.

The HTA's regulatory methods are framed by the requirements of the Human Tissue Act 2004 (HT Act) which places a specific obligation on the HTA to follow the principles of Better Regulation and to carry out regulatory activities in a way that is transparent, accountable, proportionate, consistent and targeted. The proportionate, risk-based regulatory system that we use is also informed by the good practice from key Government reports: Reducing administrative burdens: effective inspection and enforcement (Philip Hampton, 2005) and Regulation – less is more, reducing burdens, improving outcomes (Better Regulation Task Force, 2005). In April 2008 the statutory code of practice for regulators (the Regulators' Compliance Code) came into force. This provides further guidance on Better Regulation and will form the basis of an external inspection of the HTA's regulatory systems by the Better Regulation Executive during the 2008/09 business year.

The HTA works with those who need to be licensed by acting as “coach” not “cop” to bring them into the licensing framework, and to provide advice and guidance to help them to improve standards. This compliance-based approach to regulation is partnered with the HTA's proportionate approach to enforcement, which is aimed at deterring future non-compliance.

These summary inspection reports are the next steps on the path to improving standards for the regulation of human tissue. We hope that all those working in the sectors we license and inspect will review this information, and reflect on how it could be applied to their own practice to improve standards.



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Executive summary

In the period 1 September 2006 to 31 March 2008, the HTA received applications from 11 establishments requiring licences for the storage and public display of human tissue, two of which had satellites attached.

Following completion of the phase 1 inspection process, only one additional time-bound condition was placed on a licence for non-compliance with the HTA standards.

Two establishments, the Museum of Science and Industry, Manchester, and the Royal Institution of Great Britain, London, were considered high priority for inspection. One of these inspections resulted in two additional conditions being placed on the licence.

There was good compliance with the HTA standards across the board.

The majority of the establishments were not directly involved in the taking of consent, but despite this, they had a good understanding of the consent requirements of the HT Act.

Premises were deemed suitable in all cases, although advice and guidance relating to the storage and display of material was provided to the two establishments inspected in the period.

The HTA is encouraged by the sector's high level of compliance with the standards and commitment to meeting the requirements of the HT Act and codes of practice.

Introduction

1. This summary inspection report is one of a set of five. Each report is specific to one of the sectors we license and inspect. The findings in the report are drawn from two main sources of existing knowledge that are held by HTA.
 - information and data submitted by an establishment (i.e. as part of the compliance report licence application process and during the site visit inspection process)
 - documents that we have issued to establishments (i.e. drawn from site visit inspection reports and licensing decisions)
2. This report brings all the information together in one place and provides an analysis of trends and themes for the public display sector so that lessons can be learnt. The individual site visit inspection reports and proposed licensing decisions have each been reviewed by the Designated Individual (DI) responsible for supervising licensable activities in the establishment concerned. In accordance with statutory requirements, the HTA gives each Licence Holder (LH) and DI clear reasons for proposed licensing decisions and gives the establishment the opportunity to make representations about a proposal to add conditions before the HTA makes the final licensing decision. In this way, the HTA demonstrates transparency about the judgements and licensing decisions that have been made and the reasons for them. In addition, all individual licensing decisions made as a result of the findings included in inspection reports have been carefully considered with input from legal advisors and, where appropriate, a senior member of the regulation directorate. This summary report therefore draws on a wide range of pre-existing information and data that are currently held by the HTA. It is intended to provide a review and analysis of the findings from the public display sector so that the reader may consider them and, where appropriate, apply them to their own practice to enable standards to be raised across the sector.

Introduction (continued)

3. It is important to note that the conditions and advice and guidance the HTA gives to an establishment are context-specific, and do not always lend themselves to be easily or appropriately transferred to another licensed establishment. Each licensing decision the HTA makes is specific to the facts of the case and only relevant information is considered. The HTA exercises its discretion reasonably and aims to make regulatory decisions that are transparent, accountable, proportionate, consistent and targeted where action is needed. Therefore we do not routinely apply the same decision to each establishment. This means that while the HTA aims to be consistent in its decision making process, decisions will vary from establishment to establishment depending on the particular set of circumstances. So, the conditions and advice and guidance are context specific and are not always transferable to other establishments. They should be read with this in mind.

Using a risk-based regulatory approach

4. The HTA uses a risk-based regulatory approach to inform how we prioritise the phase 2 site visit inspections (see Appendix 1 for more information about the inspection process). Risk means different things to different people, according to context. So it is relevant at this point to explain what we mean by risk when referring to how we regulate. In this context, the risk the HTA refers to is regulatory risk, i.e. the risk of non-compliance with the requirements of the legislation that the HTA was set up to implement. The primary documents that inform the framework for regulatory risk are: the HT Act and the associated Regulations, including for the human application sector, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). These are therefore mandatory requirements. The legislation is supported by other documents that are developed by the HTA. Where possible, we develop this additional guidance with input from those we regulate. These documents include: codes of practice, Directions, and licensing standards.

Introduction (continued)

5. We bring the core elements of the legislation and other documents together in the licensing standards that form the basis of the compliance report licence application for each sector. The specificity and detail of regulation required for each sector is set out in the relevant legislation. Some sectors have much more detailed requirements than others. Generally, the detail of standards and requirements increase when there is a direct risk to patient safety if they are not met. The corollary is that where there are more standards with greater specificity, there is an increased risk they will not be met. Therefore the HTA focuses resources on where this is most likely to occur so that advice and guidance can be offered to help professionals achieve regulatory compliance. This means the regulatory risk of the sectors we license and inspect varies from low risk, where there is minimal regulation and a lighter touch approach can be used, to high risk, where there is detailed regulation with specific requirements and a more direct regulatory approach is employed.

Overview of public display sector and inspections 2006–2008

6. In the period 1 September 2006 to 31 March 2008, the HTA received applications from 11 establishments requiring licences for the storage and public display of human tissue, two of which had satellites attached. Nine of the applications were from establishments with permanent collections; the remaining two were from establishments that required licences for the temporary public display of human tissue (see Appendix 2).
7. Despite the small number of establishments in this sector, they vary greatly in type and size – ranging from national museums open to the public, to educational institutions accessible by students only, and small charitable organisations. Two of the establishments applied for storage licences only, as they did not intend to display publicly the material held.
8. When assessing establishments' compliance with the standards, the HTA has been proportionate and taken a risk based approach to each one, giving consideration to the type of organisation and the nature of its collection.
9. Following completion of the phase 1 inspection process (see Appendix 1), one additional condition was placed on a licence and two establishments were considered high priority for inspection. These were the Museum of Science and Industry, Manchester, which staged a Body Worlds Exhibition and the Royal Institution of Great Britain in London, which displayed several specimens on loan from another licensed establishment and imported from outside the UK during its Christmas Lecture series.

Overview of public display sector and inspections 2006–2008 (continued)

10. Neither of these establishments had exhibited human tissue before and therefore they did not have established procedures for dealing with material of this nature. Both organisations were keen to ensure that the HTA standards were met, and welcomed the opportunity for a phase 2 site visit inspection. Following phase 2 inspection, two additional conditions were placed on one of these establishment's licences, relating primarily to traceability, operating procedures and storage facilities.
11. Although the findings from these phase 2 inspections are included in this report, the focus of the report is on the findings from the phase 1 inspection process.

Compliance with HTA standards

12. There was generally good compliance with HTA standards across the board. This may be due to the museum sector's familiarity and compliance with the Department of Culture, Media and Sports (DCMS) guidance on the Care of Human Remains in Museums and the Museums, Libraries and Archives' (MLA) Museum Accreditation Scheme standards
13. Although most were registered, only two establishments were accredited by the MLA, giving them exemption from some of the HTA standards. This was an approach agreed in the early days of the HTA, when workshops were held with sector representatives to develop the HTA standards framework.
14. The consent standards were found not to apply to many establishments; four stated specifically that they did not intend to obtain further specimens and were applying for a licence to store and / or display existing holdings of material; many had systems to ensure that material would only be obtained from a licensed establishment and that it would not be accepted unless there was evidence of consent. Only one establishment appeared to be directly involved in obtaining specimens for public display.
15. Also of interest was the limited movement of material, with many establishments stating that this happens rarely, or never. In considering their response, several establishments stated that they would ensure that material was accompanied by staff to its destination to secure its safety.
16. Establishments demonstrated in their licence applications that their premises were fit for purpose. Some advice on premises was given to the Museum of Science and Industry, Manchester, and the Royal Institution of Great Britain, both before and after their phase 2 inspections, and both establishments took action promptly in response.

Compliance with HTA standards (continued)

17. The HTA is encouraged by the sector's high level of compliance with the standards and commitment to meeting the requirements of the HT Act and codes of practice. The two establishments licensed for temporary exhibitions deserve special mention. Despite their unfamiliarity with the legislation and inexperience in the display of human material, they demonstrated a commitment to meeting the standards and sensitivity to the need for respect to be shown for the dignity of the deceased.

18. The following sections of the report provide more detailed information about the findings of the phase 1 and 2 inspections.

Consent standards (C1–C3)

C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the code of practice

19. Evidence provided as compliance with this standard demonstrated that many of the licensed establishments are not involved in obtaining consent. In addition, as the consent requirements do not extend to 'existing holdings', that is material held prior to the commencement of the HT Act on 1 September 2006, nor to imported material, some establishments will never be required to seek consent.
20. Four establishments stated that they did not intend to acquire any new material; six stated that any further acquisitions would not be accepted unless consent is in line with the requirements of the HT Act and could be demonstrated, and of these, two stated that material would only be accepted via an HTA licensed establishment. Only one establishment, the Royal College of Surgeons, accepts material direct and there is a documented consent procedure that was found to comply with the HTA standards on consent.
21. One establishment stated that its acquisition and disposal policy is available on its website and it was museum policy that information about consent be stored and displayed with each item.

C2 Information about the consent process is provided and in a variety of formats

22. See C1 above.

C3 Staff involved in seeking consent receive training and support in the implications of taking consent

23. See C1 above.

Governance and quality systems standards (GQ1–GQ6)

GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process

24. Overall, the HTA found that establishments demonstrated good compliance with this standard and had documented policies and procedures in place for museum activity. In some cases, policies and procedures relating specifically to the storage and display of human remains were under review or, in one case, in development.
25. Policies and procedures cited covered the following topics:
- acquisition, disposal and loans
 - health and safety, including fire
 - collection management
 - conservation and display
 - data protection and confidentiality
 - cleaning and housekeeping
 - complaints handling
 - risk management
26. Establishments not usually engaged in the storage and display of human material had no specific procedures relating to these activities, and special advice was provided by the HTA to support them. In one case, it was recommended that a procedure be developed for the management of damage to specimens on display and also for a 'whistle-blowing' policy to be developed. In another, an additional condition placed on the licence following a phase 2 inspection, required the development of procedures relating to the licensed activity.
27. In line with DCMS guidance, the two establishments temporarily exhibiting human remains were advised to inform the public of the nature of the exhibits and ensure that the exhibits were protected from any over-enthusiastic attention paid to them by the public. In particular, recommendations were made on how to prevent exhibits being touched by children.

Governance and quality systems standards (GQ1–GQ6) (continued)

GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

28. Compliance with this standard was also good, with most of the establishments nearly or fully meeting the requirements. Whilst most establishments were able to demonstrate that they had induction and training programmes for new staff covering health and safety and introducing them to local policies and procedures, only four referred to a system of annual appraisal or personal development. Three establishments benefit from a dedicated in-house training team or learning resource centre, which supports the appraisal process and ensures that training needs are identified and the needs of individuals can be met.
29. It was often not clear from the information provided whether training programmes include specific reference to the storage and display of human tissue and whether staff involved in the handling or management of human tissue exhibits are introduced to the requirements of the HT Act and codes of practice.
30. The two establishments visited by the HTA showed great awareness of the need for respect to be shown to the specimens and for the dignity of the deceased to be maintained at all times. This was reflected in the training that was provided to staff involved in the display of specimens.

GQ3 There is a systematic and planned approach to the management of records

31. Most establishments have computerised records, which facilitate traceability of material and ensure that confidential information is protected. Documented procedures for backing up and securing data were in evidence. Three establishments stated that they use proprietary collection management software; others appear to have developed their own database systems. Paper records were also in evidence.

Governance and quality systems standards (GQ1–GQ6) (continued)

32. Following their phase 2 inspections, the two establishments were asked to implement systems to check the safety of exhibits. One was advised to create a photographic inventory list of all exhibits and a schematic of the location of each, to facilitate regular daily checks. The other was asked to keep an inventory list in the room accommodating the material, in order that a log could be maintained of the movement of specimens from and back to the storage area.

GQ4 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

33. As expected, establishments all demonstrated good compliance with this standard and most were able to describe how specimens are given unique accession numbers, and in some cases additional collection numbers. One establishment holding very few specimens had not assigned individual codes and relied on 19th Century records held by another establishment for history and source information. Because of the small number of specimens and the likelihood that additional items would not be obtained, this was considered acceptable by the HTA. Traceability of material was addressed by an additional condition in one case.

GQ5 There are systems to ensure that all adverse events are investigated promptly

34. The majority of establishments appear to have systems for reporting and managing security breaches and staff accidents; these range from use of specific incident report forms and documented reporting procedures to less formal guidance provided in training documentation. Three establishments stated that they had an emergency plan in place for dealing with severe events causing disruption to activity.

Governance and quality systems standards (GQ1–GQ6) (continued)

GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

35. All establishments demonstrated good compliance with this standard. It appears that responsibility for completing risk assessments often falls to nominated health and safety officers, either within individual departments or across the organisation as a whole, who ensure that risk assessments are reviewed regularly, remain up to date and are made available to staff. Topics included in risk assessments were:
- staff and visitor safety
 - fire
 - specimen handling
 - premises
 - use of equipment
36. Assessment of risks to specimens whilst on display or during set up and take down of exhibitions was not in evidence and advice was provided to one establishment to consider the potential risk to staff, visitors and the exhibits themselves during exhibition opening times.

Premises, facilities and equipment standards (PFE1–PFE4)

PFE1 The premises are fit for purpose

37. All establishments demonstrated that their premises are fit for purpose. Four establishments are accommodated in purpose-built or recently renovated premises and most gave examples of systems in place to ensure the security and safety of premises (see PFE3 below). Three stated that they have contingency plans should the premises become unfit for purpose. The suitability of storage of material was addressed by an additional condition in one case.
38. Some advice was offered following a phase 2 inspection relating to signage and the security and organisation of the storage area used for the material.

PFE2 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination

39. Establishments provided a range of examples to demonstrate compliance with this standard, depending on the size of the establishment and the number and type of specimens held. Those storing a small number of specimens in sealed glass cases focused on procedures to deal with damage, including access to spill kits and personal protective equipment. Others gave evidence of environmental monitoring policy and controls in place, for example formalin meters, temperature control, pest control and humidity monitoring and maintenance. One establishment storing soft tissue body parts, stores these as potential biohazards in sealed polyethylene bags or sheets.
40. Two establishments felt that they did not meet the standard, however, the HTA took a proportionate and risk-based approach and did not take any regulatory action as there was not considered to be a risk of harm to staff, visitors or the specimens themselves.

Premises, facilities and equipment standards (PFE1–PFE4) (continued)

41. In one case, an establishment displaying large exhibits was advised to undertake a risk assessment of equipment used to move exhibits around the exhibition space, to ensure its suitability for the task and the safety of staff using the equipment.
42. Guidance was given to another establishment on action to take in the event of damage to specimens during their display.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells

43. All establishments have systems in place to ensure that material is stored in a secure and safe environment, minimising the risk of theft or damage. Examples of precautions taken included:
 - regular inspections by health and safety, fire and building officers
 - dedicated storage cabinets or sealed museum cases
 - environmental monitoring
 - locked and alarmed storage areas
 - twice-yearly building and display report
 - standard operating procedures relating to safety of staff and visitors, including chaperoning
 - 24-hour security, swipe-card access and CCTV
44. One establishment was advised to consider allocation of a secure, monitored storage area for the storage of specimens removed from the main exhibition area.

Premises, facilities and equipment standards (PFE1–PFE4) (continued)

PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

45. Those establishments that are involved in the movement of material have documented procedures for specimen transfer, some of which dictate that material should be accompanied by staff. Procedures also include details of the records that should be kept.
46. One establishment undertakes a risk assessment each time a specimen is transported and has material transfer agreements in place and loan forms which are kept as part of the specimen's permanent record. Only one establishment stated that it used an outside contractor to move material. In general, movement of specimens appears to happen infrequently, with four establishments stating that it happens very rarely or never.

Disposal standards (D1–D2)

D1 There is a clear and sensitive policy for disposing of human organs and tissue

47. Six establishments stated that they had a documented disposal policy and procedure. Some of these had been updated to reflect the requirements of the HTA code of practice on disposal and one was in the early stages of development. One establishment had formed a 'remains advisory panel' to develop a policy and three considered that the standard was not applicable because the material was on loan and so responsibility for disposal did not rest with them.
48. An additional condition was placed on one licence, requiring the establishment to develop a policy and procedure on disposal, reflecting the requirements of the HTA code of practice and minimum standards.

D2 The reasons for disposal and the methods used are carefully documented.

49. Most establishments have systems in place that require decisions on disposal to be made at senior management level and records to be kept. As evidenced by standard D1, this process is not always formalised in a documented policy or procedure.

Appendix 1:

Licensing and inspection processes

The HTA defines inspection as a process encompassing desk-based review, site visit assessment and analysis of relevant written, numerical, verbal and visual information to evaluate an establishment's compliance with expected standards. Desk-based reviews are described as phase 1 inspections and site visit assessments are described as phase 2 inspections. Phase 2 inspections are primarily used to gather information that can only be gathered by going on site. Both phase 1 and phase 2 inspections lead to licensing decisions.

Phase 1 inspections

Phase 1 inspections involve a thorough analysis and evaluation of the compliance report licence application submitted by the proposed LH and the proposed DI. This information is often supplemented with additional verbal or written information requested by HTA during telephone interviews and email exchanges with the proposed DI and / or LH, as part of the process. Phase 1 inspections lead to a licensing decision including whether to grant or refuse a licence.

Phase 2 inspections

Phase 2 site visit inspections are conducted based on the findings from a phase 1 inspection plus any other relevant information. The focus during a phase 2 inspection is on reviewing an establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. This involves interviews with a range of staff at the premises. This allows the HTA to follow up any areas of non-compliance, and evaluate progress against any licence conditions imposed at a phase 1 inspection.

A risk-based approach to inspections

The HTA targets phase 2 site visit inspections at those establishments deemed to be at highest risk both across sectors and within sectors (please note, as described above, all establishments have a mandatory phase 1 desk based inspection). Risk is context-specific and we refer here to the risk of regulatory non-compliance.

Appendix 1:

Licensing and inspection processes (continued)

We also conduct phase 2 site visit inspections at low-risk establishments. This is to assess the validity of the risk assessment process we use when scheduling inspections, which helps ensure that the assessment of risk is appropriate. The phase 2 inspections also allow the HTA to gather knowledge from high performing (low-risk) organisations and to share learning about this across the sector.

Occasionally, the HTA may carry out a 'reactive' inspection. This may be announced or unannounced. The decision to carry out a reactive inspection is usually based upon receipt of information about an establishment that raises concerns regarding regulatory compliance.

The role of the HTA in making licensing decisions

The HTA has a statutory responsibility to make judgements about the suitability of the proposed Designated Individual (DI), Licence Holder (LH), premises and practices in relation to the licensed activities. This means that during a phase 1 inspection and before issuing a licence, the HTA must be satisfied that the applicant is a suitable person or entity to be the LH, and that the premises are suitable for the activities to be authorised.

The HTA must also be satisfied that the DI is a suitable person and can supervise the activities authorised by the licence. This requires the DI to have a sound knowledge and understanding of licensed activities and associated operational procedures. The HTA helps DIs to understand their statutory responsibilities by providing advice and guidance via meetings, email, workshops and training events, as well as the DI e-learning course: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders.cfm and a guide for DIs and LHs: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm

Appendix 1: Licensing and inspection processes (continued)

Although a DI's statutory responsibilities cannot be delegated, operational responsibility can be: the HTA advises DIs to identify key staff within each licensed area that can act as Persons Designated (PD) under the licence to support them in fulfilling their statutory role.

To enable the HTA to make effective judgements, we have developed standards with input from the professionals working in the sectors we license. These licensing standards form the basis of the compliance report licence application and are in four broad themes:

- consent
- governance and quality systems
- premises, facilities and equipment
- disposal

Compliance with the HTA standards is assessed through inspection, using a four-point numerical scale.

- 1 = standard not met
- 2 = standard partially met
- 3 = standard almost met
- 4 = standard fully met or exceeded

Where the inspection process identifies that a standard is not being met, formal advice and guidance may be offered or formal regulatory action may be taken where the non-compliance triggers the HTA's power to vary a licence. There are several different types of regulatory action which may be considered by the HTA: variation of licences through, for example, the imposition of additional conditions; issue of Special Directions; suspension of a licence or revocation of a licence. In the vast majority of cases, the HTA will take regulatory action by varying a licence to impose additional conditions. Additional conditions are time-bound and DIs are required to inform the HTA when they have taken appropriate action to comply with them. The HTA then assesses this information to decide whether the establishment has met the condition or whether further regulatory action should be taken.

Appendix 1:

Licensing and inspection processes (continued)

Complex regulatory issues are normally brought before a Regulatory Action Panel (RAP), to ensure that all relevant considerations are taken into account and that a fair, proportionate and justifiable licensing decision is made. RAPs are normally chaired by the Director of Regulation and consist of a Head of Regulation, a Legal Advisor and the Regulation Manager responsible for making the licensing decision.

The difference between advice and guidance and licence conditions

The HTA works as a compliance-based regulator, which means we place a strong emphasis on the value of providing advice and guidance to professionals working within the sector. This is so that they understand regulatory requirements and are better equipped to meet standards. Where enforcement is necessary, we aim to make evidence-based, justifiable and proportionate decisions. Phase 2 inspections also lead to advice and guidance from the HTA on how the establishment can improve its practices.

The HTA provides verbal and written advice and guidance in a wide variety of ways. We provide a great deal of written advice and guidance during phase 2 site visit inspections in the spirit of continuous quality improvement, and these recommendations are for the DI and staff to consider to make improvements to their systems, processes and practices. Whilst these are not statutory requirements, any advice and guidance made by the HTA is carefully considered and is intended to help establishments reflect on their practice and make improvements.

Regulatory sanctions imposed on an establishment (most frequently in the form of licence conditions) hold statutory weight and failure by the DI to comply with a licence condition is a breach of the DI's statutory duties, which gives HTA the power to revoke a licence.

Appendix 2:

List of licensed establishments in the public display sector

Permanent storage for public display

- Gordon Museum, King's College London
- National Museum Liverpool
- Natural History Museum, London
- The Old Operating Theatre Museum and Herb Garret, London
- Reading Museum
- Royal College of Surgeons, London
- Science Museum, London
- Thinktank, Birmingham Science Museum
- Wellcome Trust, London

Temporary storage for public display

- Museum of Science and Industry, Manchester
- The Royal Institution of Great Britain, London

Details of all licensed establishments are listed on the HTA website at:

www.hta.gov.uk/licensing/licensed_establishments.cfm

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