NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction for the Administration of Combined Inactivated Hepatitis A and Hepatitis B Vaccine For Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Travel_HepAB/ MGPG1259	**Review Date:** July 2024 **Expiry Date:** July 2025	**Date Approved:** July 2022

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from PHS national PGD for travel.	
Date of change	**Summary of Changes**	**Section heading**
March 2022	New PGD	

NoS Identifier: NoS/PGD/Travel_HepAB/MGPG1259
Keyword(s): PGD Patient Group Direction Hepatitis A Hepatitis B Combined Vaccine

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	March 2022
	Completed:	June 2022
	Approved:	July 2022 (published – August 2022)
	Amended & reauthorized:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

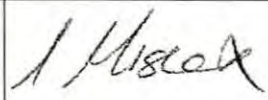
PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Daniel Chandler **Health Board:** NHST **Title:** Associate Director of Public Health / Immunisation Coordinator **Contact email:** daniel.chandler@nhs.scot **Signature** ..... **Date:** 25/07/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Sarah Buchan **Health Board:** NHSG **Title:** Pharmaceutical Care Services Manager **Contact email:** sarah.buchan3@nhs.scot **Signature** ..... **Date:** 22/07/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date:** 01/07/2022
Pharmacist	**Name:** Andrew Radley **Health Board:** NHST **Title :** Consultant in Public Health Pharmacy **Contact email:** andrew.radley@nhs.scot **Signature** ..... **Date:** 18/07/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		01/07/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		29/07/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Andrew Radley	**Pharmacist:** Consultant in Public Health Pharmacy NHST
Dr Daniel Chandler	**Medical Practitioner:** Associate Director of Public Health / Immunisation Coordinator NHST
Sarah Buchan	**Senior Representative:** Pharmaceutical Care Services Manager NHSG
Mary McFarlane	Principal Pharmacist NHSS
Russell Mackay	Clinical Pharmacist NHSO
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Jackie Agnew	Head of Community Pharmacy Services NHSH

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer combined inactivated hepatitis A and hepatitis B vaccine to individuals for active immunisation against both hepatitis A and hepatitis B (Hep A and Hep B) related to travel. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 17 and Chapter 18, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Adults and children over 1 year old who: • Intend to travel to or reside in countries where hepatitis A **and** B vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/ The risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are under 1 year of age • Have had a confirmed anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B vaccine or to any components of the vaccines, these may include neomycin (refer to relevant SmPC) • Are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation • Require vaccination unrelated to travel purposes • Require solely hepatitis B vaccination for overseas travel purposes

	• Require solely hepatitis A vaccination for overseas travel purposes • Have had a previous confirmed hepatitis B infection • Have had a previous confirmed hepatitis A infection • Are HIV positive - Seek specialist advice • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Where there is no valid consent.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. The Green Book advises there are very few individuals who cannot receive hepatitis A and hepatitis B containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine. Individuals who are solely at occupational risk of hepatitis A and/or B exposure should be referred to their employer's occupational health provider for vaccination. Individuals who have previously commenced a primary course of monovalent hepatitis A or hepatitis B vaccine should ideally continue the course with monovalent vaccines. Individuals who are immunosuppressed may not make a full antibody response. Immunological response may be diminished in those receiving immunosuppressive treatment. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated virus or bacterial vaccines or toxoids. Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks.

Action if excluded from treatment	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Individuals requiring solely hepatitis B or solely hepatitis A vaccination for overseas travel purposes, should be vaccinated with appropriate monovalent vaccines under the relevant PGD. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of a hepatitis A or B containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management. Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids). Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids). Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

<table>
<tr><td>Name form and strength of vaccine</td><td>Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), as either:

• Twinrix® Adult, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms
• Twinrix® Paediatric, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 360 ELISA units and hepatitis B surface antigen 10 micrograms
• Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms.</td></tr>
<tr><td>Legal status</td><td>Ambirix® and Twinrix® are Prescription-only Medicines (POM)

The vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.</td></tr>
<tr><td>Dosage/Maximum total dose</td><td>Dose is dependent on product, see table below.

Current UK licensed HepA/B vaccines contain different concentrations of antigen (see table below).

<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose Hep A</th><th>Dose Hep B</th><th>Volume</th></tr>
<tr><td>Twinrix® Adult</td><td>16 years or over</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0mL</td></tr>
<tr><td>Twinrix® Paediatric</td><td>One to 15 years</td><td>360 ELISA units</td><td>10 micrograms</td><td>0.5mL</td></tr>
<tr><td>Ambirix®</td><td>One to 15 years</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0mL</td></tr>
</table>
</td></tr>
</table>

	Licensed dose to provide Hepatitis A and B protection: • **Twinrix® Adult**: 1mL administered at 0, 1 and 6 months. Where insufficient time is available to allow the standard 0, 1, 6 month schedule to be completed, a schedule of three intramuscular injections given at 0, 7 and 21 days may be used. When this schedule is applied, a fourth dose is recommended 12 months after the third dose. • **Twinrix® Paediatric**: 0.5mL administered at 0, 1 and 6 months • **Ambirix®:** 1mL administered at 0 and 6-12 months For travelers, vaccines should preferably be given at least two weeks before departure but can be given up to the day of departure. If prior to departure there is only time for one dose of Twinrix® Adult or Twinrix® Paediatric to be administered, then to ensure maximum protection against hepatitis A virus, the use of monovalent hepatitis A vaccine (and therefore monovalent hepatitis B vaccine) is advised. This is due to the reduced dose of hepatitis A antigen in Twinrix® products. **Reinforcing Immunisation:** **Hepatitis A** Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk. **Hepatitis B** Travellers that have received a primary course of hepatitis B immunisation, including children vaccinated according to the routine childhood schedule, do not require a reinforcing dose of hepatitis B containing vaccine.
Frequency of dose/Duration of treatment	See Dose/Maximum total dose.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4

	When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Hep A & Hep B vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records. The vaccine should be allowed to reach room temperature before use. Upon storage, a fine white deposit with a clear colourless layer above may be observed. The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Quantity to be administered	Dose of 0.5mL to 1.0mL per administration depending on the age of the individual and vaccine product used, see Dosage/Maximum total Dose section.
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.

	Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids). If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination. If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Further information on travel health is available at https://www.fitfortravel.nhs.uk/home
Identifying and managing possible adverse reactions	Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Other commonly reported reactions include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness,

	headache, and gastrointestinal symptoms including nausea, diarrhoea and loss of appetite. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board immunisation delivery plans.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training where available • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified health professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered

	• Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Ambirix® - Date of revision of text 01/01/21, accessed15/03/22. Twinrix® - Date of revision of text 01/01/21, accessed12/03/22. Twinrix® Paediatric - Date of revision of text 01/01/21, accessed 15/03/22. British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 15/03/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Hepatitis A: the green book, chapter 17 - GOV.UK (www.gov.uk) Hepatitis B: the green book, chapter 18 - GOV.UK (www.gov.uk) American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction for the Administration of Combined Inactivated Hepatitis A and Hepatitis B Vaccine For Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction for the Administration of Combined Inactivated Hepatitis A and Hepatitis B Vaccine For Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction for the Administration of Combined Inactivated Hepatitis A and Hepatitis B Vaccine For Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**