

Accredited Safe Havens

Accreditation Process – Stage 1

Introduction

Stage 1 of the ASH accreditation process, supported by s251 of the NHS Act 2006 obtained by NHS England, has been developed to ensure data covered by the s251 continues to flow until 31st October 2013 while commissioning organisations have time to put in place business changes which will enable them to process of weakly pseudonymised data and move to full ASH accreditation.

It is expected that not all commissioning organisations will operate as an ASH.

What is an Accredited Safe Haven (ASH)?

An ASH is an accredited organisation, or a designated part of an organisation, which is contractually and legally bound to process data in ways that prevent the identity of individuals to whom the data relates from being identified.

Whilst all organisations may lawfully process data that has been anonymised through aggregation or robust pseudonymisation techniques for legitimate purposes, an ASH may process data that is only weakly pseudonymised where the data has the potential to readily identify individuals outside of the ASH environment. This data may contain a single “identifying” data item such as the NHS Number or a postcode that do not directly identify individuals but which, without the controls that apply to an ASH, render the data identifiable.

Fundamental to this, is that ASHs do not have access to other data such as that provided by the Personal Demographics Service to be able to look up the identity of individuals. The data may continue to be personal data even within an ASH but the common law duty of confidentiality is not breached by the ASH processing data in this form under the ASH controls to prevent re-identification and inappropriate use.

What is the legal framework for in the longer term Accredited Safe Havens?

Provisions in the Health & Social Care Act 2012 prohibit the Health and Social Care Information Centre (HSCIC) from releasing data in this weakly pseudonymised form to other bodies unless there are controls that prevent re-identification and a clear basis in law for circumstances where, exceptionally, the data does inadvertently identify an individual.

ASHs are provided with this lawful basis through regulations made under s251 of the NHS Act 2006. The support provided through the regulations for ASH arrangements is contingent upon an organisation complying with the conditions for accreditation and having an agreed Data Sharing Contract to reinforce compliance.

Breach of the ASH requirements e.g. by deliberately identifying an individual who's data are being processed, or where an organisation is found to be negligent in not having adequate measures to minimise the risk of unintended re-identification, will result in accreditation status being revoked, access to weakly pseudonymised HSCIC data being withdrawn and potential enforcement action by the Information Commissioner (maximum of £500k fine).

Organisations that have an ASH must maintain robust separation of ASH data from other data that may be in their possession e.g. they may have access to or hold identifiable data as a data processor

on behalf of another organisation or where there is a legal basis for processing identifiable data for other parts of their own organisation. Robust organisational and technical controls must be in place to maintain this separation.

How does an organisation become accredited?

Under s251

Stage 1 ASH Requirements:

The criteria for becoming an Accredited Safe Haven are currently under development and will change. It is expected the requirements that organisations will need to meet will be strengthened. The enhanced criteria for ASH accreditation will be published by the end of the summer so that any organisation wishing to retain accreditation will have ample time to meet these additional requirements.

The criteria at this stage are that an organisation must:

1. Have a current IG toolkit (IGT) self-assessment in place which demonstrates at least level 2 compliance against all relevant requirements for the organisation;
2. Sign a Data Sharing Contract (DSC) with the HSCIC which introduces the additional binding requirements regarding the processing, analysis and data sharing that the ASH is allowed to undertake
3. Undertake an independent audit of their IGT submission on an annual basis

1. IG Toolkit submission

Each organisation must upload their evidence into the IGT to support the self-assessment and to enable remote review. The HSCIC will review the evidence provided through the self-assessment process and the applicant must agree to the HSCIC conducting any checks or audits on the evidence that it feels are necessary. Due to these arrangements being new and recognising the need for business continuity, up to the end of September 2013, bodies seeking accreditation may not initially meet all requirements sufficiently to achieve Level 2. In these cases the HSCIC will agree action/improvement plans that will enable requirements to be satisfied in a reasonable timescale and will monitor progress.

2. Data Sharing Contract

The body seeking ASH status will also be required to complete the Data Sharing Contract which must be signed by the organisation's Caldicott Guardian or equivalent. The DSC is an overarching framework for the sharing of information setting out the high level principles and requirements and is issued once to an organisation. It is supported by a shorter Data Sharing Agreement which sets out the data being shared, the purpose, legal basis and any specific Terms and Conditions of use.

3. Independent Audit

The organisation will be required to ensure that their internal audit provider undertakes an IGT audit. The audit should take up to ten days although where internal audit plans do not address information assurance risk they may need to be adjusted to accommodate the IGT audit either in place of, or as well as, other planned work. A proposed three tier audit framework has been developed. This will be published in July. The approach covers a review of the organisations approach to delivering information governance, a high-level validation of the IG Toolkit self-assessment and a risk based review of the processes that support the IGT. Significant risk exposures may call for more detailed risk-based reviews as appropriate to the needs of the organisation. Internal audits should be carried out before toolkit submission to allow organisations time to respond to and act on the findings. The recommended overall audit opinions range from full assurance to no assurance and the accreditation requires an opinion of 'significant assurance' or above before the organisation can be accredited.

ASH Application process

- Commissioning organisations that need to become an ASH need to register their intention with: *enquiries@hscic.gov.uk*
- The HSCIC Information Governance Toolkit (IGT) Team will review the organisation's IGT submission to ensure that it meets the required standard or will make contact to assist the organisation in understanding what they need to do to achieve Level 2 of the IGT.
- The HSCIC Data Access and Information Sharing Team will draw up a Data Sharing Contract and Agreement to be signed by the applying organisation.
- A recommendation on Accreditation will be made to Secretary of State
- When the Secretary of State confirms Accreditation the successful organisations are notified
- Successful organisations will be included within a published Register on the HSCIC website
- Data Sharing Contracts and Agreements will be reviewed annually in light of each IGT submission and results from an annual independent audit of an organisations IGT

Accreditation

The initial accreditation is for an initial period up until 31st October 2013 (in-line with the s251 support) within which the applicant must provide the evidence of an independent audit of compliance with the IGT requirements and the HSCIC DSC. The accreditation processes may evolve over time and those seeking accreditation should be aware that further requirements may be introduced.

As part of the development of the ASH accreditation process, a charge for administrating the accreditation process will be considered. Organisations wishing to be accredited should also budget for the cost of the required independent audit.

The ASH accreditation process will be reviewed by the end of the summer.

Loss of Accreditation Status

Failure to meet the compliance requirements will result in the organisation losing its ASH status with the result that the HSCIC will be prohibited from providing it with data that includes weekly pseudonymised identifiers and access to data will be suspended until confirmation is received that any issues or shortfalls have been addressed.

A breach of contract, reduction in the IGT score below satisfactory level 2, or an internal audit opinion below significant assurance will result in the HSCIC reviewing the accreditation status of the organisation and may result in it being revoked.