**cMHAFF vs French HAS[[1]](#footnote-1) Good Practice Guidelines (GPG) Comparison (as of 2017-06-26)**

Numbers in parentheses (X,Y) indicate the number of conformance statements (cMHAFF) or criteria (GPG), where X=total criteria, Y=compulsory/SHALL criteria. For cMHAFF, SHALL[IF] are not included in Y.

|  |  |  |
| --- | --- | --- |
| **cMHAFF**  | **French GPG Subcategories** | **Comments** |
|  |  |  |
| Regulatory Considerations (2,1) | (Multiple) | In GPG, these are split, located specific to the criteria, e.g., Regulatory for Cybersecurity, Data Hosting, etc.  |
| Product Risk Assessment and Mitigation (7,5) | (Multiple) | Several cMHAFF criteria are covered in GPG Cybersecurity, Reliability, and Confidentiality subcategories. Also GPG 2.2 Tailoring the Scope of Assessment is a helpful framework for categorizing apps into levels of criticality |
|  | Technical Content: Technical Design (3,0) | Development methodology, update tracking, (documentation of) device configuration and performance.  |
|  | Technical Content: Data Flow (6,3) | Interface w EHR, Backward compatibility, Data import/export, Data model, Data hosting arrangements, Data backup. (Strange grouping: some are development, some are operational) |
| Product Usability (6,1) | Usability/Use: Design (12,0) | GPG covers many usability requirements (e.g., ergomics, help, flexibility, readability, accessibility, response time); cMHAFF focuses more on development process and accessibility assessment |
|  | Usability/Use: Acceptability (6,0) | Ratings/reviews (users and external groups) and adherence by users |
|  | Usability/Use: Integration/Import (6,0) | Open infrastructure, social networks; search and retrieve/print data |
| Notifications and Alerts (6,5) |  | Alerts mentioned a few times, but only for data entry error prevention or low battery  |
| App Store Experience (10,6) | Informing Users: Description (7,3) | cMHAFF category includes requirements for app descriptions, access to informationGPG category also maps to cMHAFF Nonfunctional Requirements |
| Nonfunctional Requirements: Conditions and Agreements (8,0) |  | cMHAFF includes disclosures about app payments as well as sources of evidence. Overlaps with App Store Experience category |
|  | Health Content: Design of Initial Content (11,1) | Mild overlap with cMHAFF Nonfunctional Requirements, but GPG has much more detail, e.g., user involvement, requirements methodology, author expertise, bibliographic references, level of evidence, intended use.  |
| Launch App and Establish User Account (6,2) | Health Content: Generated Content (6,4) | Slight overlap w cMHAFF in minimization of data collected, but the categories are mostly different.  |
| User Authorizations for Data Collection and Use (10,3) | Informing Users: Consent (5,5)Security/Reliability: Confidentiality (5,2) |  |
| Pairing User Accounts with Devices and Data Repositories (5,4) | Some discussion under Cybersecurity and Standardisation | Authenticating and ensuring that device is paired with the right person |
| User Authentication & Authorization to Access App Services (6,4) |  |  |
| Security for Data at Rest (3,3) | Security/Reliability: Cybersecurity (18,16) |  |
| Security for Data in Transit (1,1) |  |  |
| Data Authenticity, Provenance and Associated Metadata (4,1) |  |  |
| Audit (4,1) |  |  |
|  | Security/Reliability: Reliability (9,1) | Reliability (safety, failure detection) and availability (uptime) of hardware, sensors, software, materials, infrastructure |
| Product Upgrades (4,1) |  | Notifying user, getting permission for updates |
| App and Data Removal (7,5) |  | Removing app, local data and remote (hosted) data |
| Permitted Uses of Data Post Account Closure (1,1) |  | Restriction on further release of data |
|  | Health Content: Standardisation (6,1) | Surprisingly, cMHAFF has very little reference to standards for interoperability |
|  | Health Content: Interpreted Content (3,0) | Algorithms or human interpretation |
| Exemplary Use Cases |  | GPG doesn’t have Use Cases. |
|  | Principles 1.5.2 | Helpful to establish principles for compliance, before diving into details |
| (Multiple) | Bibliography and Literature Scan | GPG bibliography is far more extensive. cMHAFF references are sprinkled into all categories. Some cMHAFF references should be added for US-Realm.  |
|  |  |  |

1. HAS = Haute Autorité de Santé (High Authority of Health) [↑](#footnote-ref-1)