

Audiometric Medical Device/Software Approvals



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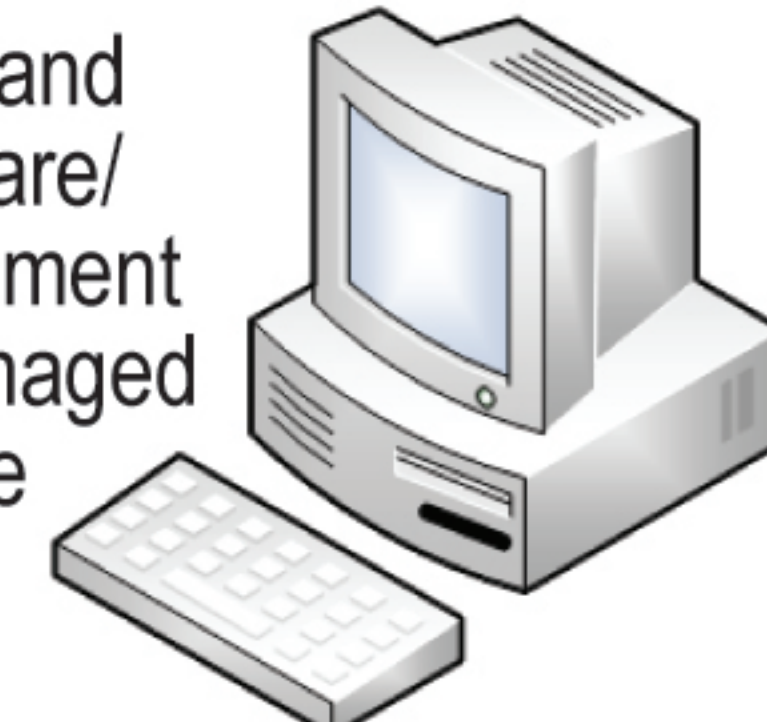
Enterprise Clinical Audiology Application (ECAA)

ECAA Clinical Diagnostic Booth (Magnified)

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Approved Products List (APL)

DHA APL staff will evaluate and certify medical device software/drivers (Otosuite, GSI Instrument Services) for use on DHA Imaged workstations connected to the DHA Medical Community of Interest (Med-COI) network.



1. Medical Device
2. ECAA Client PC
3. ECAA Server

USB Cable

1

Assess & Use (A&U)

DHA CyberLOG will evaluate each medical device and certify them for approval.



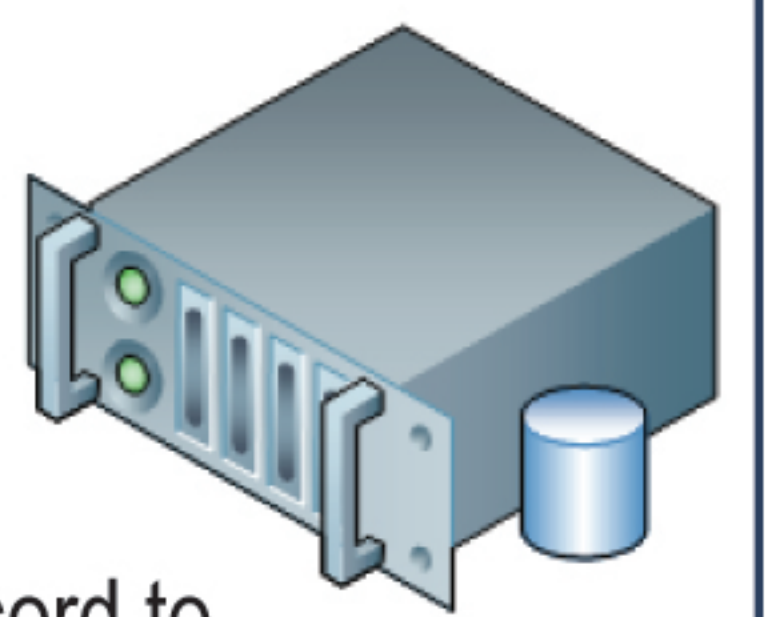
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Authority to Operate (ATO)

DHA Cybersecurity Division and HCE Cybersecurity staff maintain the Enterprise Mission Assurance Support Service (eMASS) record to meet the Risk Management Framework requirements to allow the ECAA system to operate on the DHA Med-COI network.



Source File: Created by the HCE IM Team

Hearing Center of Excellence (HCE) – Medical Device/Software Approval Effort

The HCE has been working with the Defense Health Agency (DHA) Cybersecurity Logistics (CyberLOG) team to provide enterprise-wide approval for audiometric medical devices and software. The ECAA (mandated system of use) and Noah was granted an ATO on the network. However, medical devices and software requires a different risk assessment for approval. For example, a device would receive an A&U and the software would receive a certification to be added to the APL.

Types of Risk Management Framework

- Access and Use (A&U) – Type accreditation of non-network connectivity (USB connection to PC); less than 6 months for approval.
- Approved Products List (APL) – Approval process would be completed to approve the software that would be placed on Government owned servers and workstation; 6 weeks to 3 months for approval.
- Assess and Incorporate (A&I) – Approval process for network connected devices; minimum of 6 months for approval.
- Authority to Operate (ATO) – The official management decision given by a senior organizational official to authorize operation of an information system. Time and cost vary, but a minimum of one year can be expected to receive an ATO.

Note – Only one type of accreditation is required

Where Do I Find Approved Medical Device Info?

Consolidated System Tracking & Reporting (CSTAR) – CyberLOG site for tracking approved medical devices and a tool to track the RMF status of systems within DHA purview: ATO, and Reciprocity – to include Independent Verification and Validation (IV&V) start and end dates.

<https://info.health.mil/apps/HIT/cstar?SitePages>

Where Do I Find Certified Software?

DHA APL - A list of software that has been assessed and certified by the DHA Security Control Assessor through the DHA testing process. This approval process would be completed to approve the software that would be placed on Government owned servers.

<https://info.health.mil/dadio/InfoSec/assessor/ApprovedProducts/SitePages/APL.aspx>

Do you have an audiometric device or software that needs to be risk assessed?

Please contact the HCE Information Management team to assist in submitting the risk assessment to DHA CyberLOG. Our team will work with your Information Technology department to get your device/software assessed. Send an email to our org box at: usaf.jbsa.59-mdw.mbx.hcoe-im-audiology@health.mil.

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