

NED Validation Plan v15.1 (updated July 2019)

Summary

Stage	Name	Aim
Stage 1	In-house testing	To validate in-house development of upload methodology by ERS. Upload is to the “NED Test” database.
Stage 2	First Site Validation	To validate upload methodology at First Site engaged by an ERS company. Upload initially is to the “NED Pilot” database. During this phase, if certain criteria are met, the site will switch to uploading to the ‘NED Live’ database. Upon successful completion, ERS is NED compliant and can proceed to roll out to other sites.
Stage 3	Rolling data quality assurance	To ensure data upload quality is maintained.
Stage 4	Validation for major software upgrade or NED schema iteration change	To validate any major software upgrade, ERS change or significant IT infrastructure change within the Trust
Stage 5	Procedure if upload success rate falls below 98%	Guidance to process if local or national upload success rate falls below 98%

Stage 1 - In-house testing				
<i>Validation type</i>	<i>Detail</i>	<i>Success criterion</i>	<i>Who</i>	<i>Action if criterion not achieved</i>
Term-mapping	Complete data terms mapping exercise (spreadsheet) - ensure all terms are mapped to NED terms	No orphan terms (i.e. each ERS term must map to a NED term). Minimise number of terms mapped to "other", avoid free text in binary/bit NED fields	ERS company to forward spreadsheet to NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
Upload process	Complete manual upload of Test Procedures to the "NED Test" database (available in the resources section of the NED website).	No procedures rejected by NED	ERS company	ERS company to revise software → repeat exercise
ERS/NED data accuracy	Compare data from the manual upload of Test procedures with the "NED Test" database	All mandatory data fields in NED populated accurately	NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
ERS/JETS data accuracy	Compare trainee data from the manual upload of procedures with the NED Test database	All trainee data fields for JETS populated accurately	NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
Failed upload process	ERS process for handling reports that fail to upload is required, including mechanism for informing trust, process for ensuring the required action is taken and mechanism for ensuring the corrected report is uploaded	Appropriate process developed	ERS companies to forward process outline to NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
On completion of Stage 1, proceed to Stage 2				

Stage 2 - First Site Validation				
<i>Validation type</i>	<i>Detail</i>	<i>Success criterion</i>	<i>Who</i>	<i>Action if criterion not achieved</i>
Upload process	Robust upload of live procedures to the NED Pilot database	<2% procedures rejected by NED over at least 300 procedures (USR>98%), GMC code error rate <2%	First site & ERS company; assessed by NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
ERS/NED data accuracy	Manual upload of NED Test procedures (available in the resources section of the NED website). Compare upload with NED Test database to ensure completeness and accuracy.	No major discrepancies identified	First site; to liaise with NED team (the comparison step can be automated)	NED team / First Site to liaise with ERS company → ERS revised → repeat exercise
ERS/JETS data accuracy (This step is mandatory at the first site if the version of the ERS will be used by trainees)	Compare NED and JETS data to ensure satisfactory population of the JETS database	100% accuracy for the key fields (defined in JETS testing document) where discrepancies not due to manual data entry errors	Trust SpR lead	Trust SpR Lead/First Site to liaise with ERS company/ NED team.
On completion of above steps, switch to uploading to NED Live database.				
Upload process	Robust upload of live procedures to the NED Pilot database	<2% procedures rejected by NED over at least 300 procedures (USR>98%), GMC code error rate <2%	Site & ERS company; assessed by NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
Rolling JETS monitoring/ modification by trainees	Trainees continually able to monitor and correct upload accuracy. Corrections by trainees can be monitored by NED team	JETS monitoring system working successfully	Site & ERS company; assessed by NED team	NED team to liaise with ERS company and site
On completion of Stage 2, NED-compliant status awarded to ERS company. Proceed to implementation at subsequent sites (uploading to NED Live site).				

Stage 3 - Rolling data quality assurance				
Upload process	Robust upload of procedures to the NED database	<2% procedures rejected by NED (upload success rate >98% - assessed every 3 months) See stage 6 for procedure if upload success rate is <98%	NED team	NED team to liaise with sites / ERS company → ERS revised → repeat exercise after 3 months until resolved
Rolling JETS monitoring/ modification by trainees	Trainees continually able to monitor and correct upload accuracy. Corrections by trainees can be monitored by NED team	JETS monitoring system working successfully	Site & ERS company; assessed by NED team	NED team to liaise with ERS company and site

Stage 4- Revalidation for major software upgrade or NED schema iteration change				
<i>Validation type</i>	<i>Detail</i>	<i>Success criterion</i>	<i>Who</i>	<i>Action if criterion not achieved</i>
Term-mapping	Complete data terms mapping exercise (spreadsheet) - ensure all terms are mapped to NED terms	No orphan terms (i.e. each ERS term must map to a NED term). Minimal number of terms mapped to "other"	ERS company to forward spreadsheet to NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
Upload process (performed by ERS during development)	Complete manual upload of Test Procedures to the "NED Test" database (available in the resources section of the NED website).	No procedures rejected by NED. JETS data fields accurately completed	ERS company	ERS company to revise software → repeat exercise
ERS/NED data accuracy (performed by ERS during development)	Compare data from the manual upload of Test procedures with the "NED Test" database	All mandatory data fields in NED populated accurately	NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
ERS/JETS data accuracy (performed by ERS during development)	Compare trainee data from the manual upload of test procedures with the NED Test database	All trainee data fields for JETS populated accurately	NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
ERS/NED data accuracy (performed from a test site chosen by ERS, it is recommended that this is performed in a test environment. It may be integrated with User Acceptance Testing of an ERS upgrade).	Manual upload of NED Test procedures (available in the resources section of the NED website). Compare upload with NED Test database to ensure completeness and accuracy.	No major discrepancies identified	First site; to liaise with NED team (the comparison step can be automated)	NED team / First Site to liaise with ERS company → ERS revised → repeat exercise

ERS/JETS data accuracy (performed test site chosen by ERS, it is recommended that this is performed in a test environment. It may be integrated with User Acceptance Testing of an ERS upgrade).	Compare NED and JETS data to ensure satisfactory population of the JETS database	100% accuracy for the key fields where discrepancies not due to manual data entry errors	Trust SpR lead	Trust SpR Lead/site to liaise with ERS company/ NED team.
	IF above steps are completed satisfactorily as assessed by the NED team, switch to uploading to Pilot or Live NED database using new software or NED schema			
Upload process at first site	Robust upload of live procedures to the NED Pilot or Live database	<2% procedures rejected by NED over at least 300 procedures	First site & ERS company; assessed by NED team	NED team to liaise with ERS company → ERS revised → repeat exercise
On completion of Stage 4, roll out software upgrade at other sites. Rolling data quality assurance as Stage 3				

Stage 5 – Procedure if upload success rate falls below 98%				
Validation type	Detail	Action Plans	Who	Additional actions
Upload process	<p>Robust upload of procedures to the NED database</p> <p>Metrics:</p> <p>1. Upload Success Rate (USR) Percentage of individual procedures (this is not unique procedures as the same procedure can be resubmitted multiple times) successfully uploaded to NED over a specified time period. This does not include procedures rejected for GMC code errors.</p> <p>2. GMC code error rate(GER) Percentage of individual procedures rejected by NED due to GMC code errors over a specified time period.</p> <p>3. Resubmission rate (RR) Numerator- Number of resubmitted procedures Denominator- Number for rejected procedures (includes all reasons for rejection including GMC code errors).</p>	<p><2% procedures rejected by NED.</p> <p>If Upload Success Rate (USR) falls below 98% for >300 procedures, an alert to the site, ERS and NED team will be generated.</p> <p>Days since last upload will be monitored across all ERS and sites. Units with no uploads for 48 hours are automatically alerted. If there is no upload for >1 week at review, the ERS manufacturer will be alerted.</p> <p>The alert will prompt investigation by the site and ERS into the cause for the low USR. Action depends on reason for upload failure. One or more of the following corrective measures may be necessary: -ERS company modification -Local IT changes -Local user changes</p>	NED team/ ERS manufacturer/ local NED lead and IT team	<p>GMC code error rate will be monitored by the NED system on a monthly basis and an alert sent to the site, ERS and NED team if greater than 2%. The alert will prompt the site to ensure GMC codes are up to date in the ERS.</p> <p>Resubmission rate will be presented on the NED website. All sites and ERS should aim for 100% resubmission rate.</p>

		<p>The USR will be automatically rechecked at 3 months. A further alert will be sent if below 98%.</p> <p>If the USR is persistently below 90% over 3 consecutive months or between 90% and 98% over a 6 month period, an alert will be automatically generated to the site, ERS and NED team. The alert will identify the low USR. The issue will be reviewed at the next NED team meeting and appropriate action recommended. Possible sanctions include mandating repeat Phase 2 validation (manual test procedure upload) or rescinding NED compatible status for the ERS version.</p>		
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Stage 5- Monitoring Upload Success Rate

