Current Sequence Listing Process for Nucleic Acids and Polypeptides

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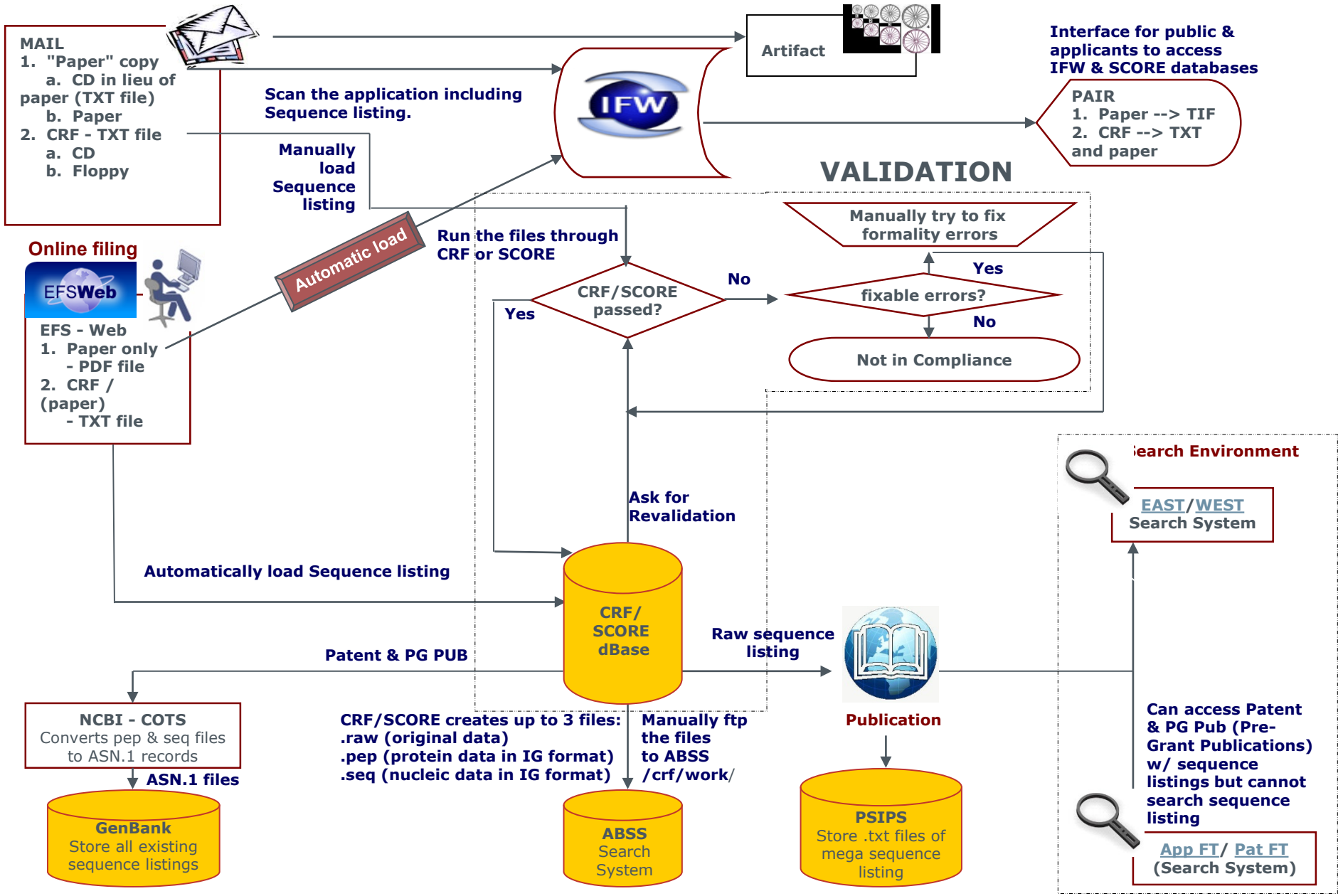
Current Sequence Listing Process

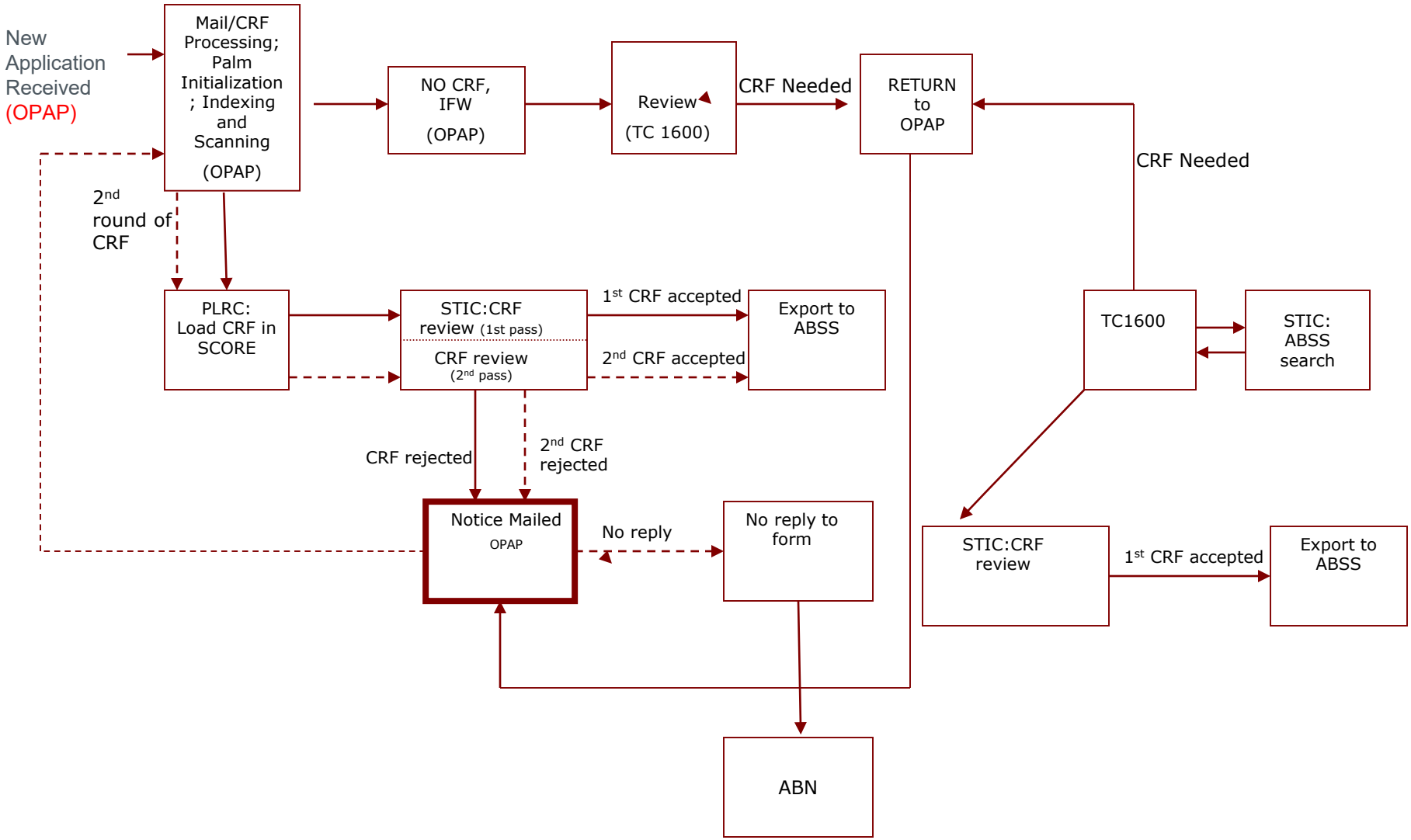
Technology Center 1600 (TC 1600) is a primary stakeholder in the current sequence listing process and is taking a major role in

- Conducting Automation Workgroup Meetings (AWG) on a biweekly basis to sustain the USPTO business function of performing quality searching of molecular sequences by TC 1600
- Sustaining the PTO's best business practices for processing genetic sequences claimed in patent applications
- Continuing to improve our business process for maintaining the infrastructure for processing molecular sequence listings and searching genetic sequences from applicant submissions and commercial databases of published sequence listings.

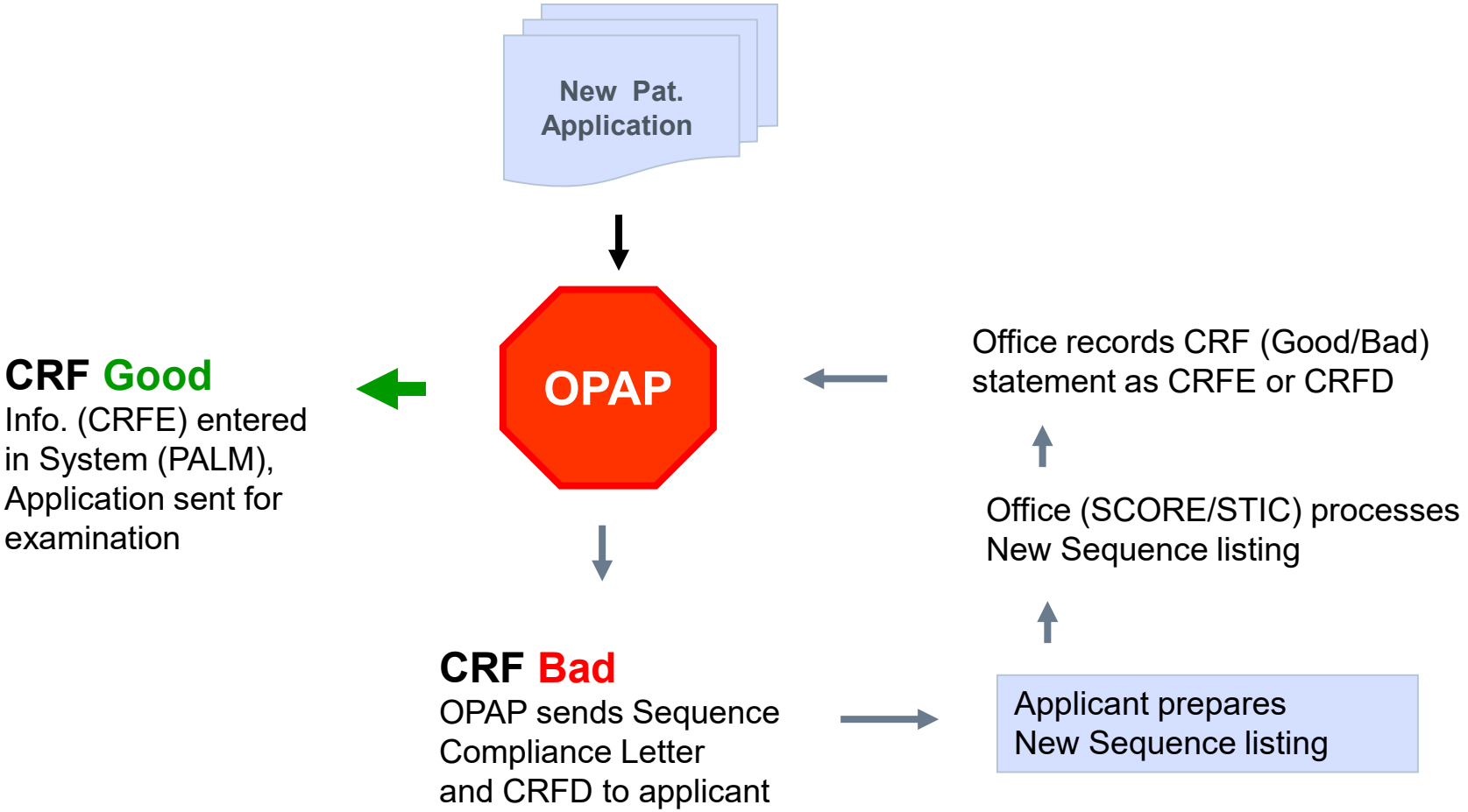
Electronic Sequence Listing Supply Chain



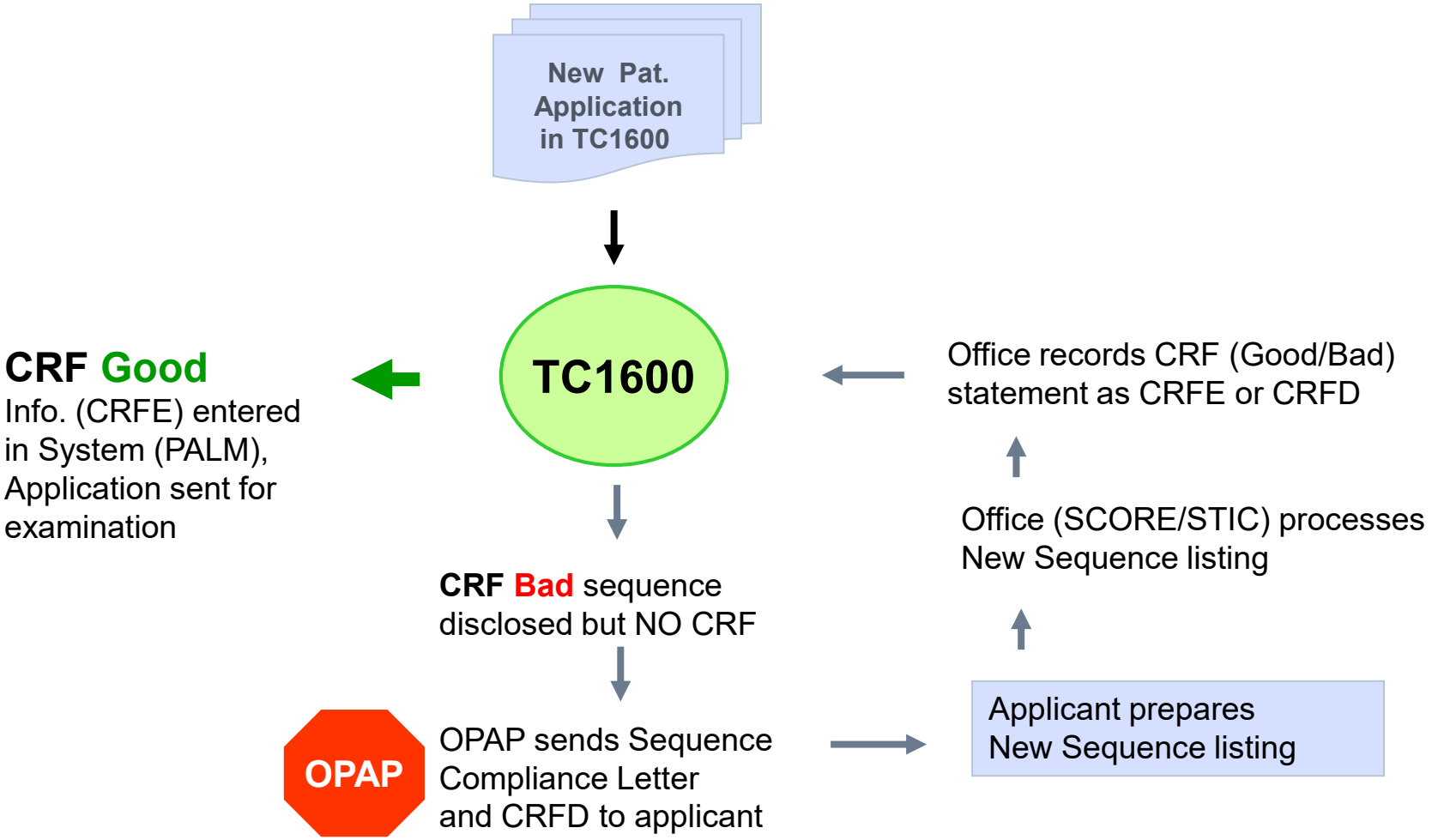
OPAP (Office of Patent Application Processing) Process Map



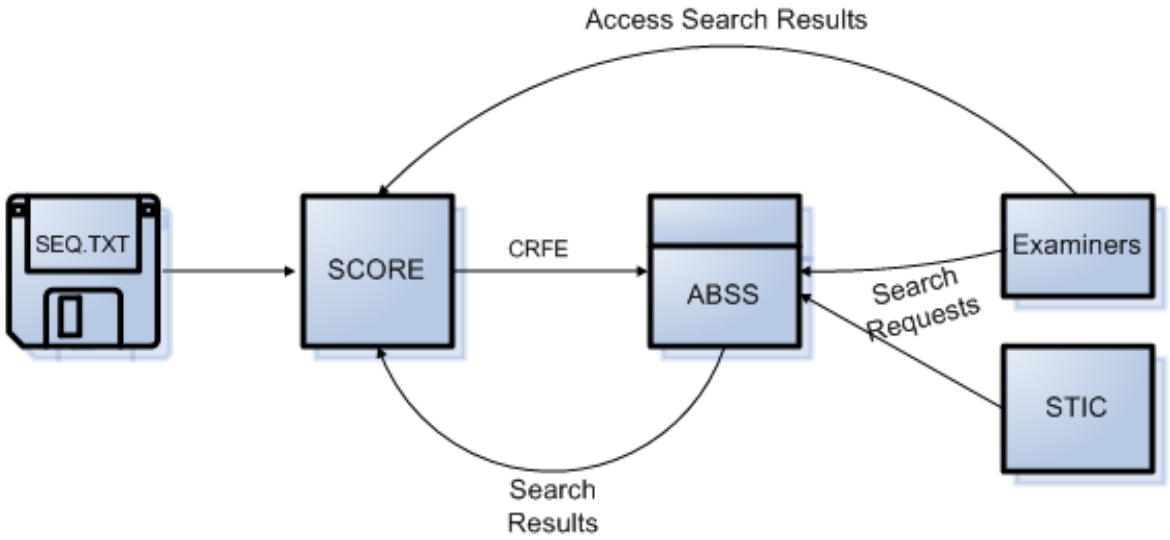
New Application Filed in OPAP



New Application in TC1600 (Status 20 or 25)

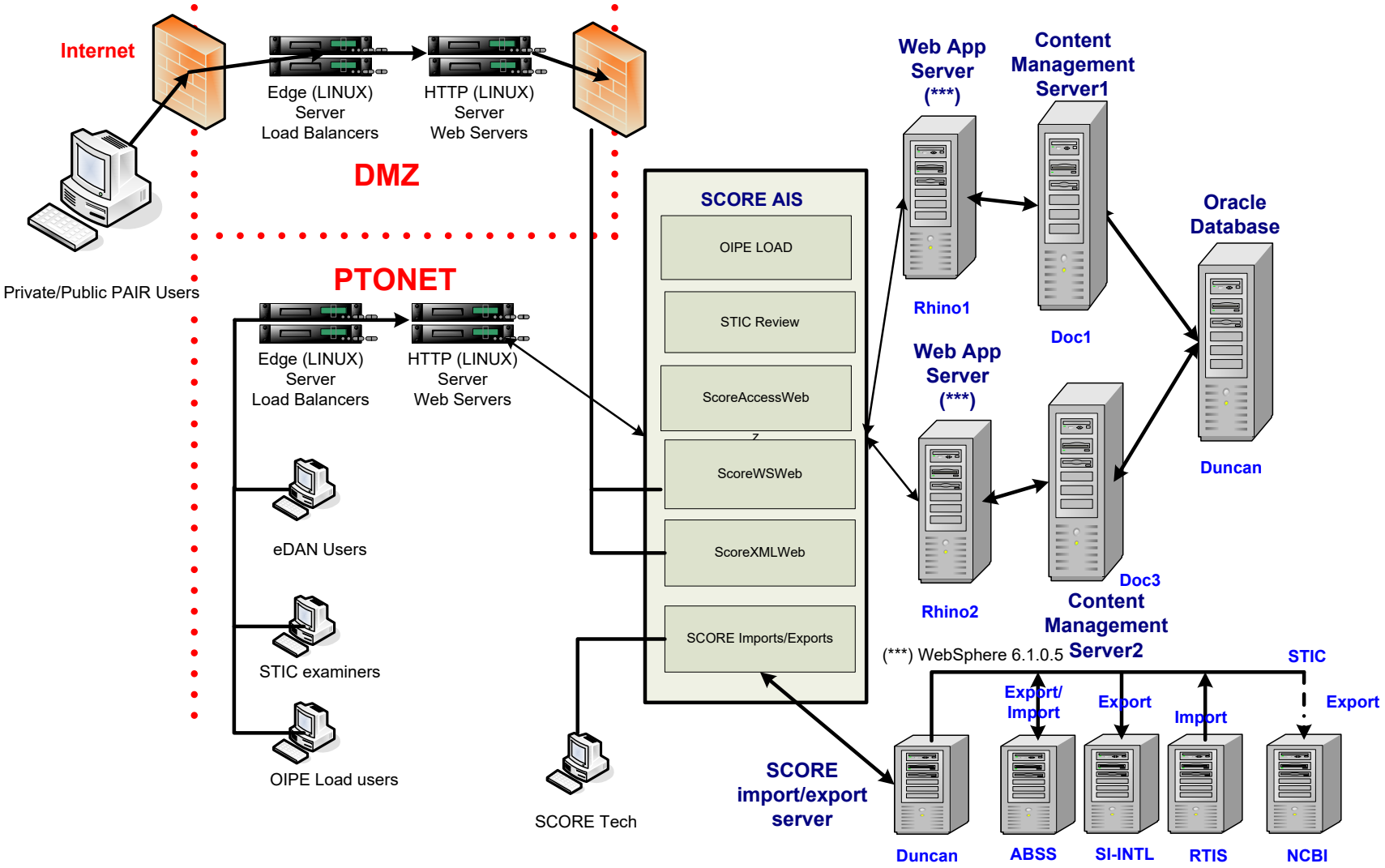


SCORE, ABSS and the Search Process



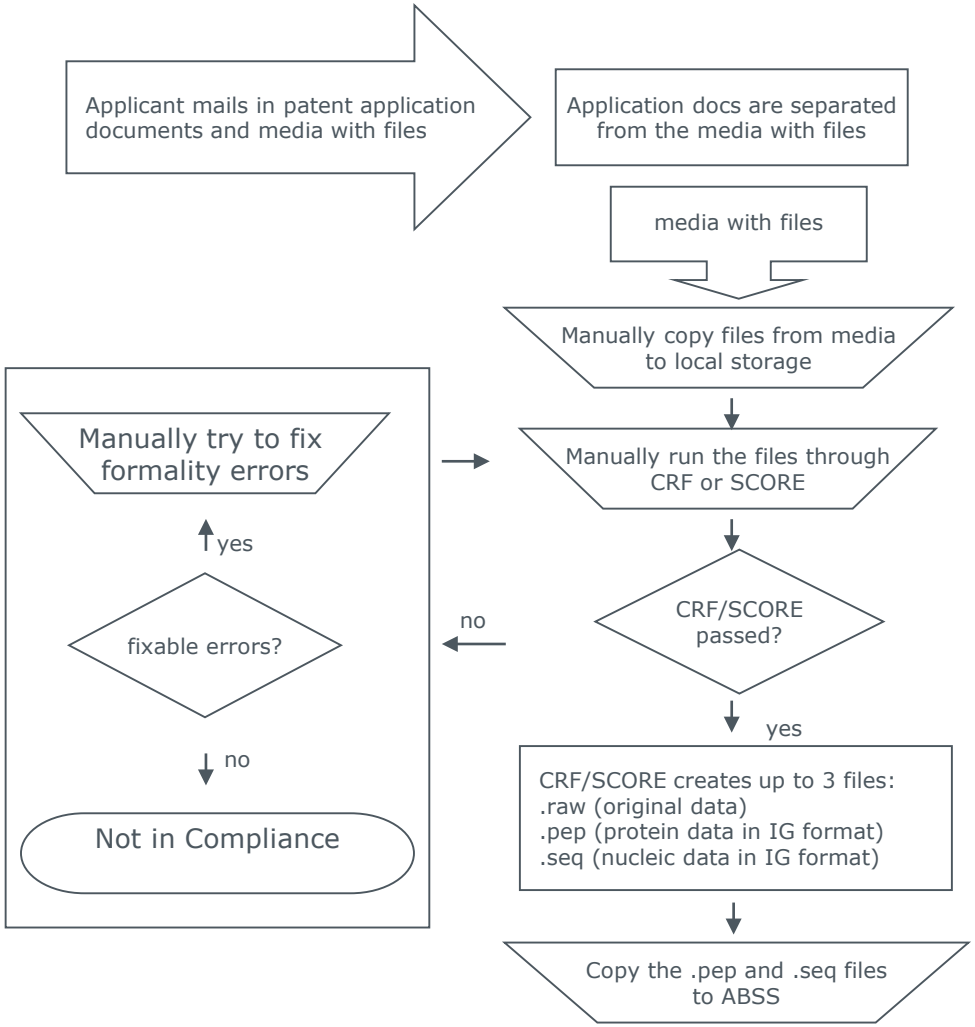
Sequence listings are loaded into SCORE. Accepted Sequence listings and then exported and stored in ABSS. Examiners and STIC submit search requests to ABSS. Once the search is complete in ABSS, the search results are routed to SCORE. The examiners access SCORE (through eDan or SCORE access web) to view the search results.

SCORE (Supplemental Complex Repository for Examiners)



System Architecture Diagram

Sequence Listing Data Flow: Processing on ABSS



Guidance on Common Issues

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What Sequence Rules Apply?

- **US Rules** - 37 CFR 1.821-825
  - Original rules -- 55 Fed. Reg. 18230 (May 1, 1990) (effective October 1, 1990)
  - Amended rules -- 63 Fed. Reg. 29620 (June 1 1998) (effective July 1, 1998).
- **International Rules** - WIPO Standard ST.25, effective July 1, 1998
  - http://www.wipo.int/standards/en/pdf/03-25-01.pdf

Common Compliance Issues

- The organism of each sequence must be defined at heading <213> (Organism) (37 CFR 1.822(b))

- Genus/species or “artificial sequence” or “unknown” must be used at heading <213>
  - Use Genus/species if at all possible
    - If it is a human sequence, for example, use Homo sapiens
    - Depends on source of the actual sequence
  - If artificial sequence or unknown, further definition is required at headings <220> - <223>

Common Compliance Issues

Artificial Sequence at heading <213>?

Explain why the sequence is artificial (not naturally-occurring)

If a portion of the sequence was derived from a natural source, e.g., a bacterial gene, then provide the source and explain how the sequence differs from the naturally occurring source material

Common Compliance Issues

Unknown

- Use if there is no scientific name disclosed or only a partial scientific name, e.g., Bacillus sp.
- Use if only the source of the organism is disclosed, e.g., “soil sample from Pittsburgh”
- Example sequence listing section:
  - <213> Unknown
  - <223> Bacillus species

Sequence Listing Examples

Example 1

```
SEQUENCE LISTING

<110>  WU, SAU-CHING
       WONG, SUI-LAM

<120>  ENGINEERED MONOMERIC STREPTAVIDIN

<130>  UNTI:026USD1

<140>  11822885
<141>  2008-05-08


<150>  11/307,576
<151>  2006-02-13

<160>  19

<170>  PatentIn version 3.3

<210>  1
<211>  159
<212>  PRT
<213>  Streptomyces sp.

<400>  1
```

Example 2

```
<210>  4
<211>  34
<212>  DNA
<213>  Artificial

<220>
<223>  Mutagenic forward primer for constructon of streptavidin mutein
       comprising single point mutation at V125

<400>  4
ggaaaagtac tcttasagga catgatacat ttac                                  3
```

Common compliance issues

- Sequences having a gap or gaps must be displayed as separate sequences in the Sequence Listing.

  For example, if a chemical moiety has several strands of protein attached to it, each protein sequence should appear in the Sequence Listing separately. The chemical moiety should NOT be shown (37 CFR 1.822(e))

- Sequences made of fragments of other sequences must be displayed as separate sequences in the Sequence Listing (37 CFR 1.822(e))

Common compliance issues

- Sequence Listings are often non-compliant because of minor formatting issues- *Use of PatentIn minimizes such occurrences*

- PatentIn's "Copy to Disk" function results in loss of hard returns on the CRF - *Regenerate the Sequence Listing and use Windows Explorer to copy the text file to the CRF*

Filing option

- Electronic Filing System (EFS) - Legal Framework:
  http://www.uspto.gov/patents/process/file/efs/guidance/New_legal_framework.jsp

Filing option

- Electronic Filing System (EFS)
  - Learn about EFS at this website: http://www.uspto.gov/ebc/efs_help.html
    - Add the sequence listing to your EFS-Web submission
    - No paper copy or statement needed for initial filing
      - If filing in response to a Notice to Comply a statement that there is no new matter is needed.
      - Sequence listing is automatically processed by SCORE and immediately placed in ABSS (if compliant)

FAQs

Why does my CRF has an error on Field Code <213>?

Numeric identifier <213> is something other than "Scientific name, i.e., Genus/species, Unknown or Artificial Sequence"

FAQs

Why does my CRF has an error on Field Code <223>?

A major reason for noncompliance is that the information provided in field <223> to explain an artificial or unknown organism is improper.

Solution:
Indicating what the artificial sequences are is acceptable, e.g., primer, aptamer, linker, adapter, cloning vector, expression vector, siRNA, probe, expressed sequence tag, etc. Chimeric constructs should identify sources of the parts, etc.

FAQs

- Do genes identified by gene accession numbers in the specification need to comply with the sequence rule requirements?

FAQs

No, they are not considered disclosures of Sequences.

When accession numbers appear in claims, they may raise an issue of improper incorporation of essential material by reference.

If the sequences need to be brought into the disclosure then they must comply with the sequence rules.

FAQs

A sequence listing was prepared via PatentIn. Why did the sequence listing submission get rejected by the Patent Office?

The USPTO uses an in-house verification software for validation. In addition, information provided in field <223> for artificial sequence or unknown organism must be manually verified.

Q and A

Thank You!

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