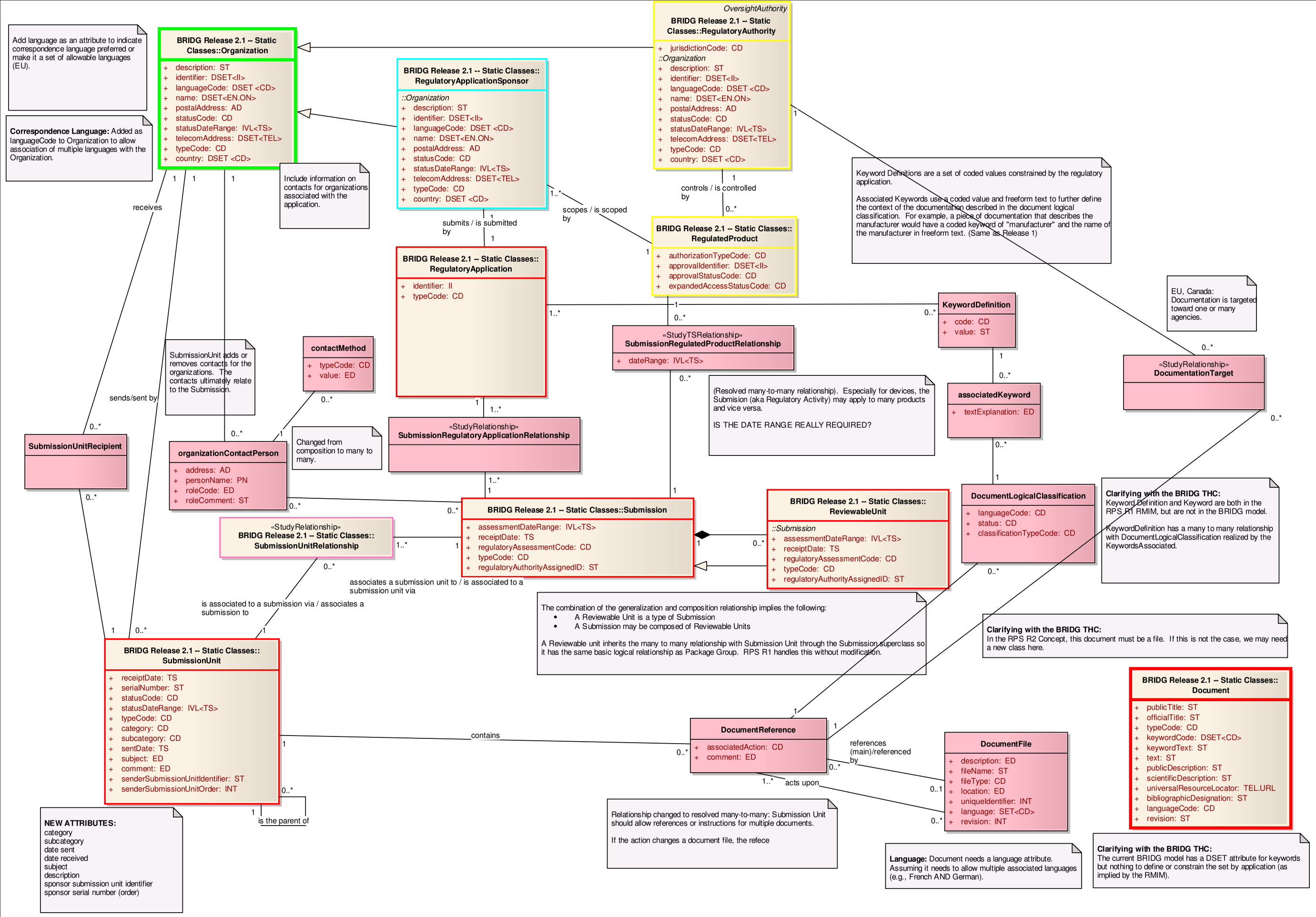
Add language as an attribute to indicate correspondence language preferred or make it a set of allowable languages (EU).
Correspondence Language: Added as languageCode to Organization to allow association of multiple languages with the Organization.
BRIDG Release 2.1 -- Static Classes::Organization
+ description: ST
+ identifier: DSET<II>
+ languageCode: DSET <CD>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
+ country: DSET <CD>
Include information on contacts for organizations associated with the application.
BRIDG Release 2.1 -- Static Classes:: RegulatoryApplicationSponsor
::Organization
+ description: ST
+ identifier: DSET<II>
+ languageCode: DSET <CD>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
+ country: DSET <CD>
OversightAuthority
BRIDG Release 2.1 -- Static Classes::RegulatoryAuthority
+ jurisdictionCode: CD
::Organization
+ description: ST
+ identifier: DSET<II>
+ languageCode: DSET <CD>
+ name: DSET<EN.ON>
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
+ country: DSET <CD>
controls / is controlled by
scopes / is scoped by
submits / is submitted by
receives
BRIDG Release 2.1 -- Static Classes:: RegulatedProduct
+ authorizationTypeCode: CD
+ approvalIdentifier: DSET<II>
+ approvalStatusCode: CD
+ expandedAccessStatusCode: CD
Keyword Definitions are a set of coded values constrained by the regulatory application.
Associated Keywords use a coded value and freeform text to further define the context of the documentation described in the document logical classification. For example, a piece of documentation that describes the manufacturer would have a coded keyword of "manufacturer" and the name of the manufacturer in freeform text. (Same as Release 1)
BRIDG Release 2.1 -- Static Classes:: RegulatoryApplication
+ identifier: II
+ typeCode: CD
KeywordDefinition
+ code: CD
+ value: ST
EU, Canada: Documentation is targeted toward one or many agencies.
«StudyTSRelationship» SubmissionRegulatedProductRelationship
+ dateRange: IVL<TS>
associatedKeyword
+ textExplanation: ED
«StudyRelationship» DocumentationTarget
(Resolved many-to-many relationship). Especially for devices, the Submision (aka Regulatory Activity) may apply to many products and vice versa.
IS THE DATE RANGE REALLY REQUIRED?
SubmissionUnit adds or removes contacts for the organizations. The contacts ultimately relate to the Submission.
contactMethod
+ typeCode: CD
+ value: ED
sends/sent by
SubmissionUnitRecipient
organizationContactPerson
+ address: AD
+ personName: PN
+ roleCode: ED
+ roleComment: ST
Changed from composition to many to many.
«StudyRelationship» SubmissionRegulatoryApplicationRelationship
BRIDG Release 2.1 -- Static Classes::Submission
+ assessmentDateRange: IVL<TS>
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
+ regulatoryAuthorityAssignedID: ST
BRIDG Release 2.1 -- Static Classes:: ReviewableUnit
::Submission
+ assessmentDateRange: IVL<TS>
+ receiptDate: TS
+ regulatoryAssessmentCode: CD
+ typeCode: CD
+ regulatoryAuthorityAssignedID: ST
DocumentLogicalClassification
+ languageCode: CD
+ status: CD
+ classificationTypeCode: CD
Clarifying with the BRIDG THC:
Keyword Definition and Keyword are both in the RPS R1 RMIM, but are not in the BRIDG model.
KeywordDefinition has a many to many relationship with DocumentLogicalClassification realized by the KeywordsAssociated.
«StudyRelationship» BRIDG Release 2.1 -- Static Classes:: SubmissionUnitRelationship
associates a submission unit to / is associated to a submission unit via
is associated to a submission via / associates a submission to
The combination of the generalization and composition relationship implies the following:
• A Reviewable Unit is a type of Submission
• A Submission may be composed of Reviewable Units
A Reviewable unit inherits the many to many relationship with Submission Unit through the Submission superclass so it has the same basic logical relationship as Package Group. RPS R1 handles this without modification.
Clarifying with the BRIDG THC:
In the RPS R2 Concept, this document must be a file. If this is not the case, we may need a new class here.
BRIDG Release 2.1 -- Static Classes:: SubmissionUnit
+ receiptDate: TS
+ serialNumber: ST
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ typeCode: CD
+ category: CD
+ subcategory: CD
+ sentDate: TS
+ subject: ED
+ comment: ED
+ senderSubmissionUnitIdentifier: ST
+ senderSubmissionUnitOrder: INT
contains
is the parent of
DocumentReference
+ associatedAction: CD
+ comment: ED
acts upon
references (main)/referenced by
DocumentFile
+ description: ED
+ fileName: ST
+ fileType: CD
+ location: ED
+ uniqueIdentifier: INT
+ language: SET<CD>
+ revision: INT
BRIDG Release 2.1 -- Static Classes:: Document
+ publicTitle: ST
+ officialTitle: ST
+ typeCode: CD
+ keywordCode: DSET<CD>
+ keywordText: ST
+ text: ST
+ publicDescription: ST
+ scientificDescription: ST
+ universalResourceLocator: TEL.URL
+ bibliographicDesignation: ST
+ languageCode: CD
+ revision: ST
NEW ATTRIBUTES:
category
subcategory
date sent
date received
subject
description
sponsor submission unit identifier
sponsor serial number (order)
Relationship changed to resolved many-to-many: Submission Unit should allow references or instructions for multiple documents.
If the action changes a document file, the refece
Language: Document needs a language attribute. Assuming it needs to allow multiple associated languages (e.g., French AND German).
Clarifying with the BRIDG THC:
The current BRIDG model has a DSET attribute for keywords but nothing to define or constrain the set by application (as implied by the RMIM).